

**Incidence of Traumatic Brain Injury, Prevalence of Dysphagia, and Factors Predicting
Health Outcomes Following Traumatic Brain Injury in Adults**

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DYSPHAGIA AND HEALTH OUTCOMES FOLLOWING TBI

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Abstract

South Africa has a high incidence of injury-related disorders, such as traumatic brain injury (TBI) as a result of motor vehicle accidents and assault. Dysphagia is a common sequela of TBI, which may result in malnutrition or aspiration pneumonia. There is limited epidemiological data available for TBI and dysphagia in South Africa which is important for health care planning. There is also inadequate literature reporting predictive factors for dysphagia and health outcomes of patients with TBI and swallowing disorders for the South African context, which would provide management guidelines for Speech-Language Pathologists (SLPs) for patients with TBI and dysphagia. This study aims to begin to provide up-to-date information regarding the incidence of TBI and the prevalence of dysphagia in the population with TBI in Bloemfontein, South Africa. Predictive factors for dysphagia and health outcomes were also investigated in order to provide management guidelines for TBI-related dysphagia for SLPs.

A prospective cohort study followed 77 participants aged 18 to 68 years ($M = 33.1$) with mild to severe traumatic brain injury, admitted to 2 state and 2 private hospitals in the Bloemfontein metropole, South Africa, to investigate the incidence of TBI and the prevalence of TBI-related dysphagia in the adult population in 2013. Participants were tracked from admission to hospital to discharge. Demographic and medical data was collected for each participant, including: gender, age, TBI aetiology, means of nutritional intake, respiratory status, length of hospital stay, and number of speech therapy sessions. Glasgow Coma Scale (GCS) scores at time of admission, swallowing evaluation, and discharge were noted as an indicator of TBI severity and each participant was assessed with the Mann Assessment of Swallowing Ability on admission and prior to discharge to assess the presence of dysphagia. The incidence of TBI for the Bloemfontein metropole was 353 per 100,000 people and was greater in the male than in the female population (11.83:1). The main mechanism for TBI in

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Bloemfontein was interpersonal violence (67.53%), followed by road traffic accidents (motor and pedestrian vehicle accidents; 23.38%). The prevalence rate for dysphagia was 32%.

Twenty-eight percent of those who presented with dysphagia also aspirated.

Severe TBI ($GCS \leq 8$) was identified as a predictive factor for dysphagia. Participants with dysphagia had longer hospital stays (days; $M = 22.04$, $SD = 17.67$) than those with normal swallowing ($M = 6.23$, $SD = 4.28$), $t(75) = 6.13$, $p < .001$, and took significantly more days to achieve oral intake ($M = 6.23$, $SD = 10.32$) than those without dysphagia ($M = .31$, $SD = 1.41$), $t(75) = 4.08$, $p < .001$. Ventilation was associated with longer hospital stays, $r_s(25) = -.47$, $p = .02$ and longer duration until achievement of oral intake, $r_s(22) = -.80$, $p < .001$. Tracheotomised participants also had significantly longer hospital stays, $r_s(25) = -.67$, $p < .001$, and took longer to achieve oral intake, $r_s(22) = -.52$, $p = .01$. An increased period of time with a tracheostomy was also significantly associated with mortality, $\chi^2(2, n = 11) = 6.52$, $p = .04$. Participants with dysphagia ($M = 3.84$, $SD = 5.44$) required significantly more therapy sessions with an SLP than those without dysphagia ($M = .15$, $SD = .64$), $t(75) = 4.85$, $p < .001$, and those with low GCS scores were significantly less likely to achieve oral intake prior to discharge, $r_s(25) = -.45$, $p = .02$, and had longer hospital stays than participants with mild head injuries, $r_s(25) = -.49$, $p = .01$. All participants who received nutrition via nasogastric tubes returned to oral intake; however, individuals who had percutaneous endoscopic gastrostomies did not achieve oral intake prior to discharge.

It is recommended that objective swallowing evaluations be conducted for patients admitted with severe TBIs, and patients with mild and moderate TBIs be screened to determine the presence of dysphagia. TBI prevention initiatives should be developed to reduce the incidence of TBI, specifically in the young adult male population.

Keywords: dysphagia, swallowing disorders, traumatic brain injury, adults,

Bloemfontein, South Africa, outcomes, predictive factors

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Glossary

Aspiration

Food or liquid entering the airway below the vocal folds (Terré & Mearin, 2007).

Dysphagia

Swallowing disorder or difficulty swallowing (Malagelada et al., 2007).

Enteral nutrition

“Feeding provided through the gastrointestinal tract via a tube, catheter, or stoma that delivers nutrients distal to the oral cavity” (Teitelbaum, Guenter, Howell, Kochevar, Roth & Seidner, 2005, p. 282).

Traumatic brain injury (TBI)

“An alteration in brain function manifest as confusion, altered level of consciousness, seizure, coma, or focal sensory or motor neurological deficit resulting from blunt or penetrating force to the head” (Bruns & Hauser, 2003, p. 2).

Introduction

South Africa is currently experiencing the pressure of a quadruple burden of disease characterised by high rates of communicable, non-communicable, perinatal and maternal, and injury-related diseases and disorders (Mayosi, Flisher, Lalloo, Sitas, Tollman & Bradshaw, 2009). The present study investigated traumatic brain injury (TBI) in the adult population and its sequelae, specifically dysphagia, to add to knowledge of injury-related disorders in South Africa and contribute to research for best practice guidelines for the management of TBI-related dysphagia.

Injury-related mortality and morbidity rates are extremely high in South Africa due to violence and road traffic accidents (RTAs; Norman, Matzopoulos, Groenewald, & Bradshaw, 2007; Seedat, van Niekerk, Jewkes, Suffla & Ratele, 2009). Norman and colleagues (2007) reported the homicide rate in South Africa to be 7 times the global average for women and 9 times for men. These authors also stated that the rate of RTAs in the country is up to 2.5 times the global average (Norman et al., 2007). These exceptionally high proportions of violence and RTAs significantly contribute to injury-related illnesses, a major component of South Africa's burden of disease (Mayosi et al., 2009).

In addition to each injury-related death there are numerous survivors left with life-altering disabilities (Krug, Sharma & Lozano, 2000). Dysphagia is a common outcome following head injury (Mackay, Morgan & Bernstein, 1999a; Mackay, Morgan & Bernstein, 1999b; Morgan, Ward, Murdoch, Kennedy & Murison, 2003; Terré & Mearin, 2007). Swallowing disorders have far reaching consequences, especially for the patient with TBI. Patients who present with dysphagia are at risk for malnutrition as difficulty swallowing directly affects their ability to eat and thus their nutritional intake (Logemann, Pepe, Mackay, 1994). These patients are also at risk for aspiration, which may result in aspiration pneumonia, compromising the respiratory health of the patient, and may even result in

death (Clavé et al., 2006). Researchers have also reported that following TBI, hypermetabolic reactions cause patients to burn more calories than usual, resulting in hyperglycaemia, and protein wasting (Cook, Peppard & Magnuson, 2008). Dysphagia may therefore be a compounding factor for poor nutritional status for patients with head injuries as a result of higher energy demands and expenditure (Mackay et al., 1999a).

A wealth of epidemiological data for TBI and dysphagia in adults is available for countries world-wide; however, little information exists for the South African population. This paper aims to provide up-to-date incidence rates of TBI and prevalence of dysphagia in the adult population with TBI in Bloemfontein, South Africa. This information is key for health care planning and delivery, TBI prevention education, and ultimately, the prevention of TBI-related dysphagia (Cassidy et al., 2004; Reilly & Ward, 2005). Predictive factors for dysphagia and health outcomes of patients with TBI and swallowing disorders are also investigated and discussed to determine appropriate assessment and management strategies to limit poor health outcomes in this population, specifically for the South African context.

Literature Review

Injury-related disorders significantly contribute to the burden of disease in South Africa (Mayosi et al., 2009). In South Africa, the main causes of injury and TBI are assault and MVAs (Nell & Brown, 1991; Norman et al., 2007; Seedat et al., 2009). A post-*apartheid* atmosphere and social issues such as the high rate of poverty, unemployment, crime, and substance abuse have been identified as factors which contribute to the high rate of interpersonal violence in South Africa (Nell & Brown, 1991; Norman et al., 2007). There is sufficient literature reporting the incidence of injuries in South Africa in general, however there is limited current information regarding the incidence of TBI. A wealth of TBI incidence data exists for countries world-wide; however, the occurrence of TBI in the South African context needs to be further researched for health care planning for hospitals and for the development of TBI prevention strategies relevant to South African (Cassidy et al., 2004; Reilly & Ward, 2005).

Literature shows a varying incidence of TBI world-wide. Table 1 summarises the incidence rates for TBI in the adult population reported by recent research studies for South Africa and internationally.

Table 1

Summary of TBI Incidence Studies World-Wide

Study authors	Year(s)	Area and population size	Study design	Sample size	Age group (years)	Inclusion criteria	Primary mechanism of TBI	Incidence/100,000	Male-female ratio
Andersson et al. (2003)	1992-1993	Western Sweden (138,000)	Retrospective and prospective cohort	489	0-99 ($M = 27$)	Mild to severe, and fatal TBI	Fall from same level (30.88%)	546	1.46:1
Baldo et al. (2003)	1996-2000	Veneto, Italy (4.48 million)	Retrospective cohort	55368	$M = 37.7$ (males); $M = 45.6$ (females)	Mild to severe, and fatal TBI	MVA (48.5%)	301 (1996) 249 (1998) 212 (2000)	1.55:1
Emejulu et al. (2010)	January 2007-December 2008	Nnewi, Nigeria	Retrospective cohort	510	0-90 +	Mild to severe TBI	Motor cycle accidents (58.8%)	2710	3.8:1
Firsching & Woischneck (2001)	1996	Germany (82 million)	Retrospective cohort	-	Children and adults	Mild to severe and, fatal TBI	MVA (56%)	350	2.45:1
Healthy People (2010)	2010	United States of America	Census data	-	$18 \leq$	All non-fatal TBIs	-	71.5 (18-44 years) 67.3 (45-64 years) 310.1 (65 years \leq)	1.71:1

(table continues)

Study authors	Year(s)	Area and population size	Study design	Sample size	Age group (years)	Inclusion criteria	Primary mechanism of TBI	Incidence/100,000	Male-female ratio
Masson et al. (2001)	1996	Aquitaine, France (2.8 million)	Prospective cohort	497	Children and adults (Mdn = 44 years)	Severe TBI	MVAs (48.3%)	17.3	2.5:1
Maset et al. (1993)	July 1986- June 1957	São Paulo, Brazil	Retrospective review	2151	Adults and children	Mild to severe TBI	-	456	-
Nell & Brown (1991)	1986	Johannesburg and Soweto, South Africa	Prospective cohort	-	15-64	Mild to severe, and fatal TBI	Assault for black South Africans (51%); MVAs for white South Africans (63%)	316	4.8:1
Rickels et al. (2010)	1 March 2000- 28 February 2001	Hanover and Münster, Germany	Prospective cohort	6783	Children and adults	Mild to severe, and fatal TBI	Falls (52.5%)	332	1.4:1
Santos et al. (2003)	1994, 1996-1997	Portugal	Retrospective review of hospital records	-	0-80 +	ICD-9 codes: 800, 801, 803, 804, 850, 851, 852, 853, 854, 907.0	-	151 (1994) 137 (1996-1997)	1.8:1

(table continues)

Study authors	Year(s)	Area and population size	Study design	Sample size	Age group (years)	Inclusion criteria	Primary mechanism of TBI	Incidence/100,000	Male-female ratio
Servadei et al. (2002a)	1998	Romagna, Italy	Prospective cohort	2430	Children and adults	Mild to severe TBI as per ICD-9 codes	-	250	1.6:1
Servadei et al. (2002b)	1998	Trentino and Romagna, Italy	Retrospective review of hospital records	4442	Children and adults	ICD-9 codes: 800.0-800.3, 801.0-801.3, 803.0-803.3, 850, 851.0-851.1, 852.0-852.1, 853.0-853.1, 854.0-854.1	Trentino: RTA (23%) Romagna: RTA (48%)	314 (Trentino) 297 (Romagna)	1.65:1
Shukri et al. (2006)	1998-2000	Aden, Yemen	Retrospective cohort	862	Children and adults	Mild to severe TBI	Domestic accidents (54.7%)	160	-
Steudel et al. (2005)	1998	Germany	Retrospective record review	276584	0-75 +	All head injury relevant ICD-9 and 10 codes	-	337	-
Yattoo & Tabish (2008)	2004	Kashmir, India (5,713,509)	Prospective cohort	3861	6 months - 80 years	Mild to severe TBI	RTA (44.4%)	55	3:1

Note. MVA = Motor vehicle accident; RTA = Road traffic accident.

The incidence of TBI ranges from 17.3 to 2710 per 100,000 as per recent international epidemiological studies (Andersson, Björklund, Emanuelson & Stålhammar, 2003; Baldo et al., 2003; Emejulu, Isiguzo, Agbasoga & Ogbuagu, 2010; Firsching & Woischneck, 2001; Healthy People, 2010; Maset, Andrade, Martucci, & Frederico, 1993; Masson et al., 2001; Nell & Brown, 1991; Rickels, Von Wild & Wenzlaff, 2010; Santos, De Sousa & Castro-Caldas, 2003; Servadei et al., 2002a; Servadei, Verlicchi, Soldano, Zanotti & Piffer, 2002b; Shukri, Bersnev & Riabukha, 2006; Steudel, Cortbus & Schwerdtfeger, 2005; Yattoo & Tabish, 2008). Bruns and Hauser (2003) conducted a review of the literature investigating the incidence of TBI throughout the world. The authors reported that globally, the incidence of TBI peaks around the adolescent and young adult years (about 15 to 25 years) as a result of spontaneous and irresponsible behaviour (Bruns & Hauser, 2003). Incidence then decreases in the adult years and rises again in the geriatric years where TBI tends to occur due to MVAs and falls, possibly due to aging of body and mind (Bruns & Hauser, 2003). In contrast to the global trend, the incidence of TBI in Johannesburg and Soweto, South Africa, was highest for the 25 to 45 year adult age range (Nell & Brown, 1991). Nell and Brown (1991) conducted a prospective cohort study in Johannesburg and Soweto in 1986 sampling from all eight hospitals within the included regions that admitted trauma cases. Results showed an overall TBI incidence of over 300 persons per 100,000 (Nell & Brown, 1991). Persons between the ages of 25 and 44 had the highest occurrence of TBI with an incidence rate of 406 per 100,000, followed by men aged 15 to 24 with an incidence of 360 per 100,000 (Nell & Brown, 1991).

Variations in methodology between each study as well as social differences of each region make direct comparisons of data challenging. Masson and colleagues (2001) only recorded the incidence of severe TBI, Healthy People (2010) reported only non-fatal TBIs, while Nell & Brown (1991), Andersson et al. (2003), Baldo et al. (2003), Emejulu et al.

(2010), Firsching and Woischneck (2001), Maset et al. (1993), Rickels et al. (2010), Shukri et al. (2006), and Yattoo and Tabish (2008) included all patients with TBI, whether fatal or not. Santos et al. (2003), Servadei et al. (2002a; 2002b), and Steudel et al. (2005) included participants according to assigned ICD codes. Some studies were retrospective reviews, including Andersson et al. (2003), Baldo et al. (2003), Emejulu et al. (2010), Firsching and Woischneck (2001), Maset et al. (1993), Santos et al. (2003), Servadei et al. (2002b), Shukri et al. (2006), and Steudel et al. (2005), while others used prospective methods to collect data, including Nell and Brown (1991), Masson et al. (2001), Rickels et al. (2010), Servadei et al. (2002a), and Yattoo and Tabish (2008). Developing regions such as Johannesburg, South Africa, São Paulo, Brazil, and particularly Nnewi, Nigeria have very high TBI incidence rates (Emejulu et al., 2010; Maset et al., 1993; Nell & Brown, 1991). Developing countries tend to have higher TBI incidence rates than higher income countries due to various poor social and economic factors (Hyder, Wunderlich, Puvanachandra, Gururaj & Kobusingye, 2007). Bruns and Hauser (2003) reported that the variations in TBI incidence are due to the unique socioeconomics, social factors and culture of communities of each area or region, which may place some societies at a higher or lower risk for TBI than others. Despite differences in research methodology, it is evident that 29 years ago, South Africa had a very high incidence rate for TBI compared to the global average (Nell & Brown, 1991).

An examination of the epidemiological data in Table 1 shows that globally, motor vehicle accidents (MVAs), road traffic accidents (RTAs) and falls were the primary causes of head injuries, however in Johannesburg, South Africa the main mechanism for TBI was assault, followed by MVAs (Nell & Brown, 1991). Norman and colleagues (2007) reported that assault accounts for 46% of all injuries and is the number one cause of general injuries in South Africa. In contrast to South Africa, MVAs and RTAs are the primary cause of injury world-wide, accounting for 25% of injuries, and assault is the number four cause of injury

world-wide, accounting for only 10% of trauma cases, after miscellaneous and self-inflicted injuries (Peden, McGee & Sharma, 2002). Nell and Brown (1991) reported that the high incidence rate of TBI in South Africa as a result of interpersonal violence may be due to social factors such as unemployment, alcohol and substance abuse, and high rates of poverty and crime in South Africa. Norman and colleagues (2007) have also suggested that a breakdown of community as a result of *apartheid* has resulted in a culture of violence-related crime in South Africa.

On a global scale, more men are admitted to hospital for head injuries than women (Andersson et al., 2003; Baldo et al., 2003; Emejulu et al., 2010; Firsching & Woischneck, 2001; Healthy People, 2010; Masson et al., 2001; Nell & Brown, 1991; Rickels et al., 2010; Santos et al., 2003; Servadei et al., 2002a; Servadei et al., 2002b; Steudel et al., 2005; Yattoo & Tabish, 2008). Nell and Brown (1991) also reported that more men than women were admitted to hospital for TBI in Johannesburg and Soweto in South Africa; where for every 1 female patient admitted, 4.8 males were admitted to hospital as a result of TBI. Men are more at risk for sustaining head injuries as they are more competitive and tend to resolve conflicts with physical violence, carry and use weapons, and take risks more than women (Bruns & Hauser, 2003; Seedat et al., 2009).

TBI is not an isolated disorder and is commonly accompanied by co-morbidities such as compromised motor functioning, cognitive, speech, and language difficulties, and swallowing disorders (Cook et al., 2008). This study focuses on dysphagia, a common consequence of TBI (Mackay et al., 1999a; Mackay et al., 1999b; Morgan et al., 2003; Terré & Mearin, 2007). Table 2 summarises the literature reporting prevalence rates for dysphagia in adults with TBI.

Table 2

Prevalence of Dysphagia Following TBI World-Wide

Study	Country or city	Year(s)	Study design	Sample size	Hospital setting	Age	Inclusion criteria	Method of assessment	Prevalence rate
Hansen et al. (2008)	Denmark	October 2000 - December 2005	Observational retrospective cohort	173	Subacute rehabilitation	16-65 years	Severe TBI	Facial oral tract therapy	93%
Mackay et al. (1999a)	USA	1992-1995	Inception cohort	54	Rehabilitation	14-70 years (<i>M</i> = 26.8)	Severe TBI	Video-fluoroscopic examination	61%
Terré & Mearin (2007)	Spain	January 2004-December 2004	Prospective cohort	48	Rehabilitation	11-63 years (<i>M</i> = 31)	Patients with severe TBI and suspected dysphagia	Clinical and video-fluoroscopic evaluation	90%

Prevalence of dysphagia among patients with TBI ranges from 61% to 93% in the adult population (Hansen, Engberg & Larsen, 2008; Mackay et al., 1999a; Terré & Mearin, 2007). These studies included only patients with severe TBI and reported very high rates of dysphagia (61% to 93%) in the adult TBI population (Hansen et al., 2008; Mackay et al., 1999a; Terré & Mearin, 2007). Mackay and colleagues (1999a) conducted research in the rehabilitation setting in order to determine the incidence of dysphagia among patients with TBI. They reported that more than half of the participants with severe TBI had dysphagia, almost half (41%) of whom also aspirated (Mackay et al., 1999a). Most recent studies conducted by Hansen et al. (2008), and Terré and Mearin (2007) reported very high prevalence rates of dysphagia (90% and 93%, respectively) in adults with severe TBI in the rehabilitation setting. Terré and Mearin (2007) also reported that aspiration occurred in about three fifths (62.5%) of the cases, of which 41% was silent aspiration.

Prevalence rates for dysphagia differ between research studies, due to variations in study design and inclusion criteria. Hansen et al. (2008), Mackay et al. (1999a), and Terré and Mearin (2007) only included patients who presented with severe TBI. Each research study was carried out within different time frames, with different methods of swallowing evaluation, employed different sample sizes, and included different age groups, as specified in Table 2. Although these variations in study methodology make evaluation of the studies difficult, it can be concluded that there is a high prevalence of dysphagia among adult patients with severe TBI (Hansen et al., 2008; Mackay et al., 1999a; Terré & Mearin, 2007). There is currently no epidemiological data reporting the prevalence of dysphagia in adults with TBI in the South African setting. This information would be valuable for health care planning, allocation of resources and budgeting at a hospital and governmental level to provide better and efficient health care services to patients with TBI (Cassidy et al., 2004).

Previous studies have identified several variables that predict health outcomes in patients with TBI-related dysphagia, including severity of TBI or GCS score, need for or length of respiratory support including tracheostomies and ventilation (Mackay et al., 1999a; Morgan et al., 2003; Ward, Green & Morton, 2007). Adult and paediatric studies found that patients with TBI who presented with swallowing disorders had significantly lower GCS scores (more severe TBI) than those with normal swallowing (Mackay et al., 1999a; Morgan et al., 2003). Mackay and colleagues (1999a) conducted a cohort study in the USA between 1992 and 1995 with 54 participants (14 to 70 years, $M = 26.8$ years) in the rehabilitation setting and determined that a low GCS score at time of admission was predictive of dysphagia in adults. Morgan et al. (2003) conducted a prospective cohort study in Australia from 1995 to 2000 with a much larger sample size of 1,145 children (1 month to 16 years, $M = 6.3$ years) in the acute hospital setting and reported that a GCS score of 8.5 or less, which is classified as severe TBI, is predictive of dysphagia. Although this paper focuses on TBI and dysphagia in adults, literature shows that regardless of age, dysphagia is associated with more severe TBI (Mackay et al., 1999a; Morgan et al., 2003).

Patients with TBI-related dysphagia appear to require ventilation for approximately 3 times longer than patients with normal swallowing (Mackay et al., 1999a; Morgan et al., 2003). Mackay and colleagues (1999a) reported that the mean ventilation period for adult patients with normal swallowing was 5.5 days, while the average period of ventilation for those with dysphagia was 13.9 days. Morgan and colleagues (2003) reported that on average, paediatric patients with dysphagia were ventilated for 5.2 days, while those with normal swallowing had a mean ventilation period of 1.4 days. Again, despite age, period of ventilation is indicative of dysphagia in patients with TBI: A ventilation period of more than 1.5 days for children and for more than 2 weeks for adults was predictive of dysphagia (Mackay et al., 1999a; Morgan et al., 2003). Mackay and colleagues (1999a) do however

warn that these results should be interpreted with care, as not all adult patients who were ventilated for more than 2 weeks had dysphagia at time of assessment, indicating that an increased period of ventilation could be an indication of more severe TBI. This cautionary advice is supported by Ward and colleagues (2007) who conducted a retrospective study in Australia with a sample of 117 patients (15-83 years, $M = 33$ years) with TBI and dysphagia who received SLP intervention during acute care. Ward et al. (2007) reported that participants with severe head injuries were ventilated for longer than those with moderate and mild head injuries (and that participants with severe TBIs took longer to initiate oral intake milestones than those with mild to moderate TBIs). The presence of a tracheostomy was also identified as a predictive factor for swallowing disorders in adult patients with TBI (Mackay et al. 1999b). Again, Mackay and colleagues (1999b) warn that this result should be interpreted with caution as dysphagia may not be a result of tracheostomy, but rather, indicative of more severe head injury.

It is common practice that patients with dysphagia receive enteral nutrition while their ability to swallow is compromised to ensure adequate nutritional intake and hydration. The literature reports that 46% to 100% of adults with TBI require enteral nutrition for full or supplemental nutritional intake at some point during hospital stay; however a large percentage (45% to 64%) of patients with TBI and dysphagia do return to total oral intake with no dietary restrictions prior to discharge (Hansen et al., 2008; Terré & Mearin, 2007; Ward et al., 2007). Ward and colleagues (2007) reported that 47% of patients who had received SLP intervention during acute care returned to total oral intake prior to discharge from hospital. Hansen and colleagues (2008) conducted an observational retrospective cohort study including 173 patients with TBI aged 16 to 65 years old ($Mdn = 33$ years) in Denmark to investigate the oral intake milestones of patients with dysphagia. The authors reported that 64% of all patients with severe TBI and dysphagia achieved total oral intake within 126 days

of being admitted to a rehabilitation facility before discharge (Hansen et al., 2008). Terré and Mearin (2007) also found that at time of discharge 45% of all patients with severe TBI achieved a normal diet prior to discharge. Although many patients do achieve total oral nutrition, a large percentage of patients with swallowing disorders do not return to unrestricted oral intake prior to discharge from hospital. In the study by Hansen and colleagues (2008), 36% of patients with dysphagia had not achieved total oral intake. Ward and colleagues (2007) reported that although 98.3% achieved some oral intake during hospitalisation, 52.2% still required dietary modifications to food, 16.5% required modifications to liquids, and 7.7% of patients had not achieved full oral intake prior to discharge and still required enteral nutrition (NGT or gastrostomy). Terré and Mearin (2007) reported that 27% of patients required a modified oral diet, 14% were receiving nutrition via gastrostomy with supplemental oral intake, and 14% were receiving nutrition via gastrostomy only.

As might be expected, patients with TBI and dysphagia take longer to initiate an oral diet and achieve total oral intake (Mackay et al., 1999a; Morgan et al., 2003), and require supplemental nutrition for longer than those with normal swallowing (Morgan et al. 2003). Ward and colleagues (2007) reported that patients with severe head injuries took significantly longer to achieve oral intake milestones than patients with moderate and mild head injuries, specifically, duration until first oral intake and achievement of a full oral diet. In support of these findings, Hansen and colleagues (2008) determined that GCS score was predictive of return to oral intake, where the lower the GCS score (and thus more severe the head injury), the less likely a patient was to achieve functional oral intake. They reported that patients admitted to the rehabilitation facility who had a GCS score of less than 9 (severe TBI) had a 41% chance of achieving full oral intake, whereas patients with a GCS score above 12 (mild TBI) on admission had a 90% chance of returning to oral intake prior to discharge (Hansen et

al., 2008). Adult data is not reported, however Morgan and colleagues (2003) also found that paediatric patients who presented with TBI-related dysphagia required longer periods of SLP intervention and had longer hospital stays than those with normal swallowing.

The prevalence of dysphagia in the TBI population is high and has a negative impact on individuals' nutritional intake (Hansen et al., 2008; Mackay et al., 1999a; Mackay et al., 1999b; Terré & Mearin, 2007). In South Africa, violence and RTAs are major causes of injury and TBI (Nell & Brown, 1991), which may exacerbate the number of persons admitted to hospitals with dysphagia. Epidemiological data for TBI and dysphagia is lacking for South Africa. This data is vital as it serves as the basis for the development of healthcare policy and protocols, sufficient healthcare service delivery, and prevention and promotion initiatives (Cassidy et al., 2004, Reilly & Ward, 2005). Risk factors for poor health outcomes in patients with TBI and dysphagia, including severity of TBI, type and duration of enteral nutrition, and respiratory status need to be further investigated in the South African context. This data will add value to best practice guidelines to achieve more effective management and better health outcomes for patients with TBI and dysphagia (Morgan et al., 2003).

Research Aims and Objectives

Aim 1

Determine the prevalence of dysphagia in patients with TBI at participating private and state hospitals in the Bloemfontein metropolitan area.

Objectives.

- 1.1. Determine the incidence of patients hospitalised for TBI
- 1.2. Determine the prevalence of dysphagia in TBI patients

Aim 2

Compare health outcomes (length of hospital stay, number of speech therapy sessions, period of enteral nutrition, period until commencement of oral intake, period of time until total oral intake is achieved, method of nutrition at discharge, and mortality) of patients with TBI, with and without dysphagia.

Aim 3

Compare patients with and without dysphagia on GCS score at admission and at time of swallowing evaluation, and identify factors, such as severity of TBI and ventilation period, that predict dysphagia.

Aim 4

Determine correlations and associations between patient variables (including age, severity of TBI, type and duration of enteral nutrition, and respiratory status) and health outcomes (specifically length of hospital stay, return to oral intake, length of time taken until commencement of oral intake, length of time until total oral intake is achieved, method of nutrition at discharge, and mortality) in patients with TBI who present with dysphagia.

Methodology

Research Design

This study adopted a prospective cohort design consisting of a group of patients with TBI. Cohort studies are observational and longitudinal in nature and are thus suited for the collection of epidemiological data, risk assessment, and determining correlations between multiple participant variables and outcomes as they develop over time (Johnson, 2012; Rothman, 2012). In the present study, a study sample of patients with TBI was selected in order to determine the incidence of TBI and prevalence of dysphagia in patients hospitalised for TBI. Participants in the cohort who did not present with dysphagia made up an internal comparison group against which health outcome variables of patients with dysphagia could be assessed in order to determine possible predictive factors for dysphagia, such as severity of TBI and period of ventilation (Stommel & Willis, 2004). Furthermore, associations between participant variables and health outcomes could be identified in patients who presented with dysphagia (Johnson, 2012).

Cohort studies often require large sample sizes and as a result tend to be costly (Johnson, 2012); however, patients with TBI are known to have a high prevalence of dysphagia (Mackay et al., 1999a; Terré & Mearin, 2007) and therefore a large enough sample size could be achieved over a short period of time and research costs could be minimised. Attrition is an inherent problem of longitudinal research as participants tend to be lost to follow-up over the course of data collection, resulting in data being lost or incomplete and inaccuracy of results (Ahern & Le Brocque, 2005). In the present study, no participants were lost to follow-up as all participants were in-patients and were monitored on a daily basis at the participating hospitals by the researcher. The researcher was also able to locate patients on the hospitals' data base if they were transferred between participating hospitals. Furthermore, the attending doctors and nursing staff often contacted the researcher before

participants were discharged as the researcher had indicated need for follow-up prior to discharge in the patients' hospital folders.

Participants

Inclusion criteria. Individuals were eligible for inclusion in the study if they were 18 years or older and had been admitted to any of the participating hospitals with a diagnosis of TBI.

Exclusion criteria. Patients were excluded if they had any significant neck or facial injuries, or a history of previous TBI, stroke, head or neck surgery, dysphagia, or any disorder or disease that may have affected swallowing pre-morbidly.

Sampling Method

Purposive sampling was used to create a cohort with characteristics specific to the population being studied (Durrheim & Painter, 2008), that is, patients with TBI aged 18 years and older. Purposive sampling is prone to researcher bias (Polit & Beck, 2010); however as inclusion and exclusion criteria were clearly specified and based on the diagnosis of TBI by doctors and radiologists, researcher bias was minimised. Purposive sampling does not allow for results to be generalised to the broader population, however results from the current study can be applied to populations in similar contexts (Durrheim & Painter, 2008). Results from the present study can thus be applied to patients admitted to hospital with TBI in South Africa or to hospitals with similar health care facilities, such as high care and intensive care units, and trauma or emergency medicine departments where trauma cases can be managed.

Sample Size

Prior to data collection, sample size was calculated based on results reported in similar studies (Mackay et al., 1999a; Mackay et al., 1999b; Terré & Mearin, 2007; Ward et al., 2007) using Stata 12 (StataCorp, 2011). A sample size of 66 to 119 participants was

necessary to achieve a power of .8, with the alpha level for statistical significance of the test set at .05. A total of 164 patients with TBI were admitted to the participating hospitals over a period of 3 months; 158 of whom were admitted to state hospitals and six of whom were admitted to private hospitals. Of these patients; 17 patients died and eight were transferred to other hospitals (that were not taking part in the study) before they could be recruited or assessed, eight patients had significant facial or neck injuries, two had neurological disorders that may have effected swallowing ability, another two had previous head injuries and surgery, and one patient was not medically stable for the duration of the data collection period and were thus excluded from the study. In addition, 49 patients were unconscious or confused and did not have capacity to provide informed consent (and did not have proxies that could provide consent) and were excluded from the study, with the exception of being anonymously counted for incidence data. Patients who met the study inclusion criteria and for whom written informed consent was obtained (from the patient or their proxy) were included in the study, achieving a sample size of 77 participants. Figure 1 (Appendix A) details the recruitment process with regards to inclusion and exclusion of participants for the study.

Recruitment

Following ethics approval for the study, staff at the participating hospitals working in the trauma and emergency units, and in wards where patients with TBI are typically admitted were briefed regarding the study. Admission records were reviewed daily by the researcher in order to identify potential research participants. All patient information viewed on admission records was kept confidential. Attending nurses asked potential participants for permission for the researcher to contact them. When permission was granted, the researcher met with each patient to inform and invite him/her to participate in the study.

Participants were recruited from four hospitals in the Bloemfontein metropole:

Hospitals.

1. Two public hospitals (one tertiary level hospital and one regional hospital with 636 and 758 beds, respectively)
2. Two private hospitals (with 133 and 127 beds, respectively)

One public hospital and one private hospital were situated close to a township and informal settlement on the outskirts of Bloemfontein. The other public and private hospitals were situated in an urban area close to the city centre.

Participant description

Table 3 shows the demographic and medical data of participants in the cohort who presented with and without dysphagia. The cohort group included 77 patients (most of whom were admitted to state hospitals in Bloemfontein) with an average age of 33.1 years ($SD = 12.2$, $range = 18$ to 68 years). More than two thirds of the head injuries sustained by participants were as a result of assault (67.53%), followed by motor vehicle accidents (MVAs; 14.29%), pedestrian vehicle accidents (PVAs; 9.09%), and falls and miscellaneous accidents (9.09%). On admission to hospital, more than half (59.74%) of the participants had mild TBIs (Mdn GCS = 13, $SD = 3.7$, $range = 4$ to 15), approximately one fifth (22.08%) had severe head injuries, and 19.48% had moderate TBIs. Twenty-five participants presented with dysphagia (approximately a third of the cohort group), the majority of whom (40%) presented with severe dysphagia, 32% presented with moderate and 28% with mild dysphagia, as per the Mann Assessment of Swallowing Ability (MASA) rating scale. Twenty-eight percent of participants who presented with dysphagia aspirated during the swallowing evaluation and were found to have severe dysphagia (as per the MASA). The 52 participants who did not present with dysphagia acted as an internal comparison group against which the participants with swallowing disorders were compared.

Table 3

Participant Demographic and Medical Data

Participant descriptive data	Participants with dysphagia		Participants without dysphagia		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Gender						
Male	22	28.57	49	63.64	71	92.21
Female	3	3.9	3	3.9	6	7.79
Hospital						
State	24	31.17	52	67.53	76	98.7
Private	1	1.3	0	0	1	1.3
Aetiology of TBI						
Assault	12	15.58	40	51.95	52	67.53
MVA	8	10.4	3	3.9	11	14.29
PVA	4	0.05	3	6.9	7	9.09
Falls & other accidents	1	1.3	6	7.79	7	9.09
TBI severity on admission						
Mild (GCS \geq 13)	5	6.49	40	51.95	45	59.74
Moderate ($9 \leq$ GCS \leq 12)	8	10.4	7	9.09	15	19.48
Severe (GCS \leq 8)	12	15.58	5	6.49	17	22.08
Severity of dysphagia						
Mild	7	9.09				
Moderate	8	10.4				
Severe	10	12.99				
Aspiration	7	9.09				

Note. MVA = Motor vehicle accident; PVA = Pedestrian vehicle accident; GCS = Glasgow Coma Scale.

The mean ages of the participants with dysphagia and the comparison group (of participants without dysphagia) were not significantly different as can be seen in Table 4.

Table 4

Comparison of the Ages of Participants With and Without Dysphagia

Participants with dysphagia (<i>n</i> = 25)			Participants with normal swallowing (<i>n</i> = 52)			<i>t</i>
Mean age	<i>SD</i>	<i>range</i>	Mean age	<i>SD</i>	<i>range</i>	
34.6	12.49	19-68	32.4	12.17	18-62	.72

Tools and Assessments

Glasgow Coma Scale. The GCS is a non-invasive, standardised tool used to determine the severity of coma, impaired consciousness, and TBI in patients (Khan, Baguley & Cameron, 2003; Teasdale & Jennett, 1974). Assessment is based on eye opening and responses to verbal and motor stimuli which are scored out of a total of 15 (Bruns & Hauser, 2003). A score of 13 to 15 is regarded as *mild*, 9 to 12 as *moderate*, and a score of 9 or less is considered *severe* TBI (Bruns & Hauser, 2003). The GCS is widely accepted and well established tool used to monitor patients with head injuries during hospital stay and determining severity of brain injury and outcomes after TBI (Bruns & Hauser, 2003; Khan et al., 2003; McNett, 2007; Teasdale & Jennett, 1974). Teasdale, Knill-Jones and van der Sande (1978), using observer variability methods, found the GCS to be reliable and practical and not biased towards any culture or language. It has also been shown to have good construct validity (Lindsay, Carlin, Kennedy, Fry, McInnes, & Teasdale, 1981), reliability (Prasad, 1996), and intra-rater reliability for experienced users (Fischer et al., 2010). Although the GCS is an ideal tool for assessment of patients with TBI, the accuracy of assessment scores may be compromised by certain conditions, such as periorbital oedema, which may affect patients' ability to open their eyes, aphasia or the presence of a tracheostomy tube which may underestimate patients' verbal responses, and spinal cord injury which may limit motor responses (Flannery, 1998). When used to monitor patients' recovery in hospital, the validity of the GCS may decrease over time, as patients may recover past the scope of the assessment,

however still present with cognitive fallout not represented by the GCS score (Flannery, 1998).

In the current study, the GCS was routinely used by doctors at all the hospitals participating in the study to determine severity of TBI for patients. Doctors recorded GCS scores in participants' hospital folders each day which were then used (by the researcher) to determine the severity of brain injury for the purpose of this study.

The Mann Assessment of Swallowing Ability. The MASA is an assessment tool for the clinical evaluation of dysphagia and aspiration in patients, 18 years and older, with neurological disorders (Mann, 2002). The MASA includes the evaluation of speech, language and cognitive ability, respiratory status, oral motor function, and actual swallows with various bolus consistencies for functional swallowing ability (Mann, 2002). It is administered in 15 to 20 minutes and has been shown to be reliable for determining severity of dysphagia and aspiration in patients with stroke (Mann, 2002). Dysphagia and aspiration are scored out of a total of 200 and then ranked according to a severity scale: *No abnormality detected, mild, moderate* or *severe* (Mann, 2002). The MASA has good face, content, and concurrent validity; comparing well to other validated assessments of swallowing, such as the 3 oz water swallow test, developed by DePippo, Holas, and Reding (1992), and includes all necessary areas of assessment (Crary, Mann & Groher, 2005; Mann, 2002). Cronbach's alpha correlation was used to evaluate the reliability of the content of the MASA (Mann, 2002). Cronbach's alpha coefficient for the entire assessment was .8817, indicating that the MASA has good internal consistency and reliability (Mann, 2002). To determine inter-rater reliability for the MASA, kappa values were determined for the evaluation of dysphagia and aspiration. The kappa score for the agreement between two independent evaluators for dysphagia was .82, indicating *excellent* agreement, and the kappa score for identification of aspiration was .75, which is interpreted as *good*, according to the definition of agreement by

Landis and Koch (1977), which was employed for the MASA (Mann, 2002). It should be noted that although the MASA was validated with patients with stroke, the assessment is also intended for patients with various neurological disorders or injury (Mann, 2002).

The MASA was used for the current study as it could be administered independently by the researcher, who is a qualified SLP and therefore, the case loads of other health professionals' working at the participating hospitals were not unnecessarily burdened during the period of data collection. Videofluoroscopic examination (VFSS) is the preferred method for assessment of dysphagia and aspiration (Costa, 2010); however, the researcher would have required access to the hospitals' radiographic departments and equipment, as well as assistance from a radiologist and radiographers for assessing each research participant, which would have burdened the radiology departments' case loads. Furthermore, some of the participating patients had limited mobility due to their head (or other) injuries, which would have limited access to the radiology department for VFSS.

Screener for determining capacity to provide informed consent. An informal screener (Appendix B) developed by the researcher to determine patients' capacity to provide informed consent was adapted from screening questions and guidelines from Appelbaum (2007) and Grisso and Appelbaum (1998) and was approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee for use in the research study. Appelbaum (2007) and Grisso and Appelbaum (1998) suggest an array of 16 questions for assessment to determine patients' capacity to provide informed consent. Patients with TBIs may have attention deficits following their head injury (Hart, Whyte, Kim, & Vaccaro, 2005) and therefore may not be able to cope with answering such an extensive list of questions. To hasten the screening process and thus accommodate patients with TBIs, seven key questions were selected from the array of questions suggested by Appelbaum (2007) and Grisso and Appelbaum (1998) which cover all the recommended criteria for assessing capacity to

provide informed consent. The language of the questions was simplified to better accommodate lay participants. The selection of seven basic key questions resulted in a screener for determining patients' capacity to provide informed consent that could be quickly administered to lay participants. The selected questions evaluate patients' understanding of the information presented to them, appreciation of their medical condition, ability to reason by considering the risks and benefits of research participation, as well as ability to provide consistent responses regarding their choice to participate or not (Appelbaum, 2007; Grisso & Appelbaum, 1998). If patients were able to answer all seven questions by providing appropriate responses, indicating that they understood the nature of the research and what they would be required to do, and were able to consistently indicate whether they would like to participate in the research study or not, they were considered to have the capacity to provide (or decline) informed consent.

Research Personnel

Translators. Two seSotho-English speaking doctors and two Afrikaans-English speaking doctors were recruited to assist with translation of the patient information sheet and consent form from English to seSotho and to Afrikaans (which are languages commonly spoken in Bloemfontein). These documents were then back-translated by the researcher (who is English-Afrikaans speaking) and by one of the recruited interpreters (who is seSotho-English speaking) to check for accuracy of the information.

Interpreters. Two seSotho-English speaking individuals were recruited and trained by the researcher to assist with interpreting and with informing patients (or their proxies) about the study, determining patients' capacity to give informed consent, and obtaining consent from patients who did not understand or speak English or Afrikaans (which are languages spoken by the primary researcher). Both interpreters were trained in the field of health sciences and were either employed at or working in the hospital where their

interpretation services were needed; one was a final year dietetics student and the other, a qualified Speech-Language Pathologist and Audiologist. The researcher reviewed and explained the patient information sheet, consent form, and screener used to determine capacity to give informed consent to the two interpreters. Each interpreter practiced asking the questions or explaining the information to two bilingual English-seSotho speaking volunteers who then relayed the information back to the researcher in English. Training continued until the researcher determined that the information could be accurately communicated. As both interpreters were health professionals, they were aware of the research participants' right to confidentiality, but this requirement was reiterated, as was the requirement to keep all participant information confidential.

Primary researcher and research assistants. The primary researcher and two research assistants were responsible for the assessment of research participants swallowing for data collection. The researcher is a qualified SLP registered with the Health Professions Council of South Africa (HPCSA) with clinical experience in the assessment and management of dysphagia. Two research assistants were trained by the researcher to administer the MASA to assist the researcher with collecting data and ensuring consistency of test administration and inter-rater reliability. One assistant is a qualified SLP and the other, a qualified SLP and Audiologist. Both research assistants were registered with the HPCSA and have clinical experience in the assessment and management of dysphagia. The researcher and research assistants learnt to use the MASA as per the instructions in the MASA training manual. The administration of the assessment was practiced on two (of the same) volunteers who had no history of swallowing problems in order to become familiar with the evaluation protocol before assessing pilot study participants.

Procedures

Ethics approval (Appendix C) for the study was obtained from the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (UCT FHS HREC # 502/2013) and permission was obtained from each of the hospital managers and hospital ethics committees (Appendix D) to conduct the research at two state and two private hospitals in the Bloemfontein area. The healthcare staff in each of the hospitals' trauma and intensive care units and wards, where patients with TBI are typically admitted, were briefed by the researcher regarding the nature and purpose of the study.

The researcher visited each hospital on a daily basis over a three month period (September to December 2013) to review admission records to identify patients who met the inclusion criteria for the research study. Attending hospital staff were requested to assist with recruitment by asking potential participants for permission for the researcher to contact them. Once such permission was given, the researcher met with each patient at a convenient time that did not conflict with other health care procedures or rehabilitation that they may have been receiving. Patients' were given an information letter and the nature of the study and participant requirements were explained verbally to each patient (or to their proxy in cases where the patient did not have the capacity to provide consent) in their preferred language by the researcher or interpreter. Patients who were unconscious, confused, or not alert at the time of admission were recruited when they had recovered and were awake and alert. Patients were excluded from the study if they did not have the capacity to provide informed consent, if consent could not be obtained from the patient's proxy, or participation in the study was refused, with the exception of being anonymously counted for the purpose of incidence data. If the patient (or patient's proxy) agreed to participation in the study and it was determined that they had the capacity to provide informed consent, they were requested to sign a consent form (also in their preferred language).

After obtaining written informed consent, participants' hospital folders were reviewed to obtain relevant demographic and medical information. Each participant's gender, date of birth and age, TBI aetiology, means of nutritional intake, and GCS score (as an indicator of TBI severity) on admission and at time of swallowing evaluation were recorded. GCS scores were determined and recorded by doctors in the wards who routinely used the tool. Personal information including participant and proxy names and contact information (telephone numbers) were also noted in case participants needed to be contacted prior to discharge for a follow-up assessment or to collect any missing information at the end of the data collection period. Personal information was kept separate from demographic and medical data collected for the purposes of the study objectives and does not appear in this study report or any disseminated results.

All participants were assessed with the MASA by the researcher and a research assistant within 2 days of admission and recruitment, or when medically stable in order to ensure timely detection of swallowing difficulties. The mean number of days between admission and assessment was 3.31 days ($SD = 4.47$, $range = 0$ to 25 days). Each participant was assessed in the following areas, as specified by the MASA: alertness, cooperation, auditory comprehension, respiratory status, presence of language and speech disorders, and oral motor function (Mann, 2002). Results were recorded on a response form for each participant at the time of assessment. Participants' verbal responses were audio recorded and later checked to ensure accuracy of scoring. Based on participant responses, it was determined whether it was safe to continue with the assessment of actual swallows. If it was determined to be unsafe to continue, the researcher returned at a later time and reassessed the patient. Once it was safe to continue, participants were positioned in an upright sitting position, with support if required, for the swallowing evaluation. The MASA does not specify the bolus consistencies required for the swallowing evaluation and so a protocol was

adopted from Logemann, Veis and Colangelo (1999). Participants were presented with a 1 ml water bolus, half of a teaspoon semi-solid bolus (smooth yoghurt), and a solid bolus (one quarter of a small biscuit), in this sequence (Logemann et al., 1999). Each bolus consistency was presented twice, unless the participant aspirated, in which case the specific bolus consistency was not repeated and the participant was given time to recover before presenting a different consistency. If the researcher felt that it was unsafe to continue, the assessment was terminated. Participants who presented with dysphagia, speech, or language difficulties were referred to the hospital speech therapy department for further management. Patient referrals were not a burden on the SLTs case loads as participants with speech, language, or swallowing difficulties would have been referred by other attending medical staff at a later time.

To address inter-rater reliability for the administration of the MASA every 10th participant was assessed simultaneously but independently by the researcher and a research assistant who were blind to each other's recording. Assessment scores assigned by the researcher and research assistants were converted to dysphagia severity rankings (*no abnormality detected, mild, moderate, or severe dysphagia*) as per the MASA and statistically analysed to determine the level of agreement between raters. Severity rankings were used as they are more indicative of swallowing ability than numerical scores. To address intra-rater reliability, the researcher reassessed each participant within 1 day of initial evaluation and blinded to the initial assessment scores. Once again, MASA scores were converted to dysphagia severity rankings and statistically analysed to determine the level of agreement of participants' swallow function at initial and second administration of the MASA. Inter- and intra-rater reliability results are reported in the Reliability section. Each participant was re-evaluated by the researcher with the MASA within 2 days prior to discharge (hospital staff routinely noted when patients were expected to be discharged or the

researcher was called by attending staff prior to patient discharge). Participants' respiratory status, type and duration of enteral nutrition, duration until initiation of oral intake, duration until total oral intake was achieved, method of nutrition at discharge, number of speech therapy sessions, and length of hospital stay were noted from participants' medical records on discharge. All hospital staff in the relevant wards and the hospital managers were informed verbally and with written notification when the data collection period came to an end.

Pilot Study

The pilot study provided an opportunity for the researcher and the two research assistants to gain experience conducting the MASA with patients with TBI. Familiarity with the MASA allowed for improved intra- and inter-rater reliability and thus accurate assessment results for the main study. The feasibility of the study data collection procedures, as well as accessibility to patients, and the conduciveness of the various hospital wards for the administration of the MASA were assessed during the pilot study (Leon, Davis & Kraemer, 2011).

Pilot participants. Ten participants that met the inclusion criteria for the study were recruited on admission to the participating hospitals for the pilot study. Pilot study participants were not included in the main study.

Pilot study procedures. Each pilot study participant was evaluated by the researcher as well as by a research assistant who scored participants' responses simultaneously, but independently, and blinded to the researcher's record for the purpose of determining the level of inter-rater reliability. The researcher also re-assessed and scored each pilot participant again within 1 day of initial assessment to ensure the consistency of recording of assessment results and to determine the level of intra-rater reliability. MASA scores were converted to ordinal rankings (*no abnormality detected, mild, moderate, or severe dysphagia*), as per the

MASA, and statistically analysed with weighted kappa (with linear weighting and a confidence interval of .95) to determine the level of inter- and intra-rater reliability.

Results of the pilot study. The hospital wards were conducive for data collection and the hospital staff were cooperative and willing to assist with the recruitment of participants. The steps taken to collect data proved feasible and thus no modifications were made to the study procedures. Based on the time taken to recruit 10 participants for the pilot study, it was predicted that an adequate number of participants would be recruited for the main study during the 3 month data collection period.

The kappa value for inter-rater reliability for the pilot study was .82, indicating a *very good* level of agreement (Fleiss, 1981). The kappa value for intra-rater reliability was .84, also indicating a *very good* level of agreement (Fleiss, 1981). Administration of the MASA was therefore consistent and reliable and thus an acceptable tool for data collection for the main study. The results of the pilot study were not used in the main study.

Reliability

In this section, the reliability of assessment and research procedures for the main study is addressed. Reliability refers to how accurate a measurement tool is in rendering the same results on repeated administrations (Durrheim & Painter, 2008). Inter-rater reliability refers to the homogeneity of scores of different test administrators for the same test (Singh, 2007).

Inter-rater reliability was determined to ensure the reliability of the administration of the MASA by the researcher and the two research assistants. MASA scores collected by the researcher and research assistants for reliability purposes (as described in the procedures) were statistically analysed with weighted kappa (with linear weighting and a confidence interval of .95) in order to determine the level of intra- and inter-rater reliability for the

administration of the MASA. The kappa value for inter-rater reliability was .74, which is interpreted as *good* (Fleiss, 1981). Intra-rater reliability is the extent of concordance of repeated administrations and scoring of a test by the same person (Waltz, Strickland & Lenz; 2010) and was determined to ensure that the researcher was consistent when administering the MASA to research participants for the duration of the data collection period. The kappa value for intra-rater reliability was 1, indicating *very good* agreement (Fleiss, 1981). Therefore, administration of the MASA during data collection was consistent and assessment scores allocated to participants were accurate.

Data Analyses

Data management. Data was cleaned and missing information was obtained from participants' hospital records. Data for the study and control group were entered and analysed in Microsoft Excel (2010) and Statistica (12; StatSoft, Inc., 2013). The alpha level for statistical significance was set at .05 for all analyses.

Description of data. Measures of central tendency were used to describe patient demographic and medical data: mean for interval variables (age, period of time: hospitalised, with a tracheostomy, of ventilation, and enteral nutrition, duration until initiation of oral intake, and total oral intake, and number of speech therapy sessions), and median for ordinal variables (GCS scores; Durrheim, 2008; Terre Blanche, 2006). Measures of variability; range, standard deviation and variance were applied to describe data variability for patient demographic and medical data and assessment outcomes (Durrheim, 2008; Terre Blanche, 2006).

Epidemiology. All patients admitted to the participating hospitals with a diagnosis of TBI, regardless of exclusion criteria, were included for the calculation of incidence of TBI per 100,000 over a 3 month period in Bloemfontein. Incidence rate was calculated by dividing

the number of TBI incidents by the number of patients admitted with TBI multiplied by the duration of data collection (Bonita, Beaglehole, Kjellström, 2006). To obtain an estimate of the incidence of TBI over the course of a year, the incidence rate for 3 months was multiplied by 4. As only four of six relevant hospitals took part in the study, the yearly incidence rate was multiplied by the total number of beds of all six hospitals (2282 beds) and divided by the total number of beds of the participating hospitals (1654 beds) to obtain an estimate of the TBI incidence rate for the Bloemfontein Metropole. Prevalence of dysphagia in the TBI population was calculated by determining the percentage of patients who presented with dysphagia within the participating TBI population (Bonita et al., 2006) who met the inclusion criteria for the study and from whom consent was obtained.

Comparison of health outcomes of TBI patients with and without dysphagia.

Differences in health outcome data were measured and described and t-tests for independent groups were applied in order to compare health outcomes of patients with and without dysphagia (Nunez, 2006).

Comparison of GCS scores of patients with and without dysphagia and factors predicting dysphagia. For the comparison of GCS scores at admission and SLP evaluation of participants with and without dysphagia within the cohort, t-tests for independent groups and Mann-Whitney U-tests were applied to determine whether there was any difference in the mean or median values (Lachenicht, 2006). Logistic regression and odds ratio were used to yield predictive factors for dysphagia and determine the likelihood of having dysphagia (Kleinbaum & Klein, 2002).

Health outcomes in patients with TBI and dysphagia. For the analysis of demographic and medical variable data Pearson's product-moment correlation, Spearman's coefficient of rank correlation, and chi-square tests were applied to determine whether

associations exist between demographic and medical variables and health outcomes for participants who presented with dysphagia. Demographic and medical variables included in the analysis were age, TBI severity rankings, type and duration of enteral nutrition, and respiratory status. Health outcomes included in the analysis were length of hospital stay, return to oral intake, duration until initiation of oral intake, duration until total oral intake is achieved, method of nutrition at discharge, and mortality. Correlation analyses for duration of enteral nutrition and duration until initiation of oral intake, and achievement of total oral intake were not determined as they are intrinsically related.

Ethical Considerations

The following ethical principles were upheld, as outlined in The Declaration of Helsinki (World Medical Association, 2013), for this study:

Autonomy. Autonomy emphasises the right of persons to make their own decisions without persuasion and manipulation by another party (Wassenaar, 2008). Written informed consent for voluntary participation was obtained from each participant included in the study. Consent forms were translated into Afrikaans and seSotho (which are commonly spoken languages in Bloemfontein), and an interpreter was made available for those who could not communicate in English or Afrikaans (the languages spoken by the researcher) in order to explain the study, determine patients' capacity to give informed consent, and respond to patients' questions regarding the study. If any patient did not have the capacity to give written informed consent due to health reasons, language, or cognitive fallout as a result of TBI, informed consent was obtained from the patient's proxy, that is, the patient's legal representative or next of kin, such as spouse or parent (Wagner, 2008). In the event that a proxy could not be identified for the patient or the proxy refused or was not able to give informed consent for the patient's participation in the study, the patient was excluded from the study and was only anonymously counted for epidemiological data. All patients and their

proxies were informed that participation was voluntary and that they may discontinue participation in the study at any time without having to provide a reason.

Confidentiality. Confidentiality requires researchers to protect and respect participants' privacy (Wassenaar, 2008). Participants' private information was kept confidential and participants' names and contact details were kept separate to the collected data and stored on a password protected computer and deleted when all data had been analysed. Personal and contact details were collected in case participants needed to be contacted prior to discharge for a follow-up assessment or to collect any missing data at the end of the data collection period. The names and identifying information of participants' do not appear in the written study report or in any dissemination of the results.

Beneficence. Beneficence asserts that the researcher should show consideration for the participants' welfare (Babbie, 2013). There were no material benefits for taking part in this study, which was made known to the all patients (and their proxies) prior to obtaining consent to participate in the study. Research participants who required speech, language, or dysphagia therapy were referred to the hospitals' speech therapy departments for further management.

Nonmaleficence. Nonmaleficence refers to the duty of the researcher to not harm the research participants (Wassenaar, 2008). The MASA, which was chosen for the detection of dysphagia, does not involve any risk beyond routine clinical evaluations of swallowing and was conducted by the researcher who is a qualified SLP experienced in the assessment of dysphagia. Although the assessment of actual swallows may have posed some risk of choking or aspiration to participants that had dysphagia; clinical evaluation of swallowing in patients with TBI is standard of care and TBI patients are routinely assessed by SLPs for the presence of dysphagia with actual swallows (Bardien et al., 2011).

In order to reduce the risk of choking or aspiration, participants were positioned in an upright position (MASA, 2002). To ensure oral hygiene, the oral cavity of each participant was checked for food residue prior to the swallowing evaluation, which was removed and cleaned if present. Water boluses were presented first as water presents a low risk for lung infection if aspirated because it has a neutral pH (Scharver, Hammond, Goldstein, 2009). Only small bolus volumes, which would not block the airway, were presented during the assessment (Logemann et al., 1999). If any patient choked or aspirated on any bolus during the assessment, the specific bolus consistency was not repeated and the participant was allowed to recover before continuing the assessment with another bolus consistency if it was safe to do so. If the researcher felt that it was not safe to continue, the evaluation was discontinued. Participants who presented with speech, language, communication difficulties, dysphagia, or aspiration were referred to the hospitals' speech therapy departments for management.

Justice. The principle of justice obligates the researcher to be just, non-biased, not to take advantage of any participant, and to make benefits from the research available to the sample population (Wassenaar, 2008). Participants were managed fairly and according to their individual health related needs. While research findings do not directly benefit the study participants, they may benefit other patients with TBI.

Results

Results are reported in accordance with the stated aims and objectives of the study.

Incidence of TBI and Prevalence of Dysphagia Following TBI in Adults

The incidence of TBI for persons 18 years and older was approximately 353 per 100,000 people over a 1 year period in the Bloemfontein metropole (after adjusting to account for the two hospitals that did not participate in the study). The TBI incidence ratio for males and females was 11.83:1. The prevalence of dysphagia following TBI was 32% (25 of 77 participants) over the 3 month period.

Comparison of Health Outcomes in TBI Patients With and Without Dysphagia

Descriptive data was compared to determine differences between groups of participants with and without dysphagia.

Mortality. Four participants died during the data collection period, three (75%) of whom had dysphagia, and one (25%) who had normal swallowing.

Nutritional intake upon discharge. Upon discharge, all 52 participants who had normal swallowing on admission were still receiving full oral intake and a normal diet. In contrast, 16 participants (64%) who had initially presented with dysphagia were receiving a normal diet, two (8%) were on a soft diet, three (12%) were receiving a liquid diet, and four (16%) were still receiving enteral feeds at discharge (or prior to death). Therefore, although most participants with dysphagia had achieved total oral intake with no dietary restrictions, 36% of participants still either required consistency modifications to compensate for swallowing difficulties ($n = 5$; 20%), or still required enteral nutrition and had not returned to oral intake ($n = 4$; 16%) upon discharge.

Table 5 compares the health outcomes of participants with and without dysphagia.

Table 5

Comparison of Health Outcome Measures of Participants With and Without Dysphagia

Participant variables	Participants with dysphagia (n = 25)			Participants without dysphagia (n = 52)			df	t
	M	SD	range	M	SD	range		
Length of hospital stay (days)	22.04	17.67	4-58	6.23	4.28	2-25	75	6.13***
Period of enteral nutrition (days)	10.6	16.51	0-53	.25	1.2	0-8	75	4.53***
Duration until initiation of oral intake (days)	5.41	9.2	0-38	.38	1.39	0-8	72	3.87***
Duration until total oral intake achieved (days)	6.23	10.32	0-40	.31	1.41	0-9	72	4.08***
Number of speech therapy sessions	3.84	5.44	0-19	.15	.64	0-4	75	4.85***

Note. *** $p < .001$.

Participants with dysphagia had significantly longer hospital stays, and required more speech therapy sessions than participants without dysphagia. Participants with dysphagia also received enteral nutrition for a significantly longer period of time, and took significantly longer to commence with oral intake, and to achieve total oral intake than those without dysphagia.

Factors Predicting Dysphagia

GCS scores. Table 6 shows the median GCS scores of participants with and without dysphagia. The median GCS scores at time of hospital admission and swallowing evaluation of the group with dysphagia were significantly lower than those of participants with normal swallowing. This indicates that participants with dysphagia had more severe head injuries than those without dysphagia.

Table 6

Median GCS Scores of Participants With and Without Dysphagia

Variables	Mdn GCS scores		U	z
	With dysphagia	Without dysphagia		
GCS score on admission	10	14	245	-4.40***
GCS score at assessment	14	15	187	-5.03***

Note. *** $p < .001$.

Severity of TBI. Logistic regression and odds ratio results for variables predicting dysphagia are given in Table 7.

Table 7

Logistic Regression and Odds Ratios Predicting Dysphagia Following TBI and Ventilation

Variables	OR	95% CI	LOD
TBI severity on admission			2.59
Mild	1		
Moderate	9.14	[8.32, 9.96]	
Severe	19.20***	[18.37, 20.03]	
Ventilation period (days)	1.80	[.97, 3.33]	3.53

Note. LOD = log odds ratio. *** $p < .001$.

Log odds ratio indicates that participants with TBIs were almost three times more likely to have dysphagia. More specifically, significant odds ratio indicates that participants with severe head injuries on admission were 19.20 times more likely to have dysphagia than participants with less severe head injuries (mild and moderate TBI), suggesting that severe TBI is predictive of dysphagia. Significant odds ratios show that participants with moderate head injuries were also more likely to have dysphagia; however, this result was not statistically significant.

Period of ventilation. Participants with dysphagia ($M = 2.96$, $SD = 4.07$) had significantly longer ventilation periods than those without dysphagia ($M = .29$, $SD = 1.19$), $t(75) = 4.39$, $p < .001$. Table 7 shows results for logistic regression and odds ratio for period

of ventilation in participants with TBI. Log odds ratio indicates that participants who were ventilated were 3.53 times more likely to have swallowing disorders than those who were not ventilated. Furthermore, participants with longer ventilation periods had greater odds ($OR = 1.8$) of having dysphagia; however this result is not statistically significant.

Correlations and Associations Between Participant Variables and Health Outcomes of Patients With Dysphagia

Age of participants. Age was not correlated with length of hospital stay, $r(20) = -.28, p = .21$, period of enteral nutrition, $r(20) = -.31, p = .17$, duration until initiation of oral intake $r(20) = -.3, p = .17$, or duration until total oral intake is achieved, $r(20) = -.32, p = .15$.

Severity of TBI. Table 8 shows correlations between TBI severity ratings (as determined by GCS scores) and health outcomes for participants with dysphagia.

Table 8

Correlations Between TBI Severity Ratings and Health Outcomes for Participants With Dysphagia

Health outcomes	TBI severity ratings			
	Admission		Dysphagia assessment	
	r_s	df	r_s	df
Length of hospital stay (days)	-.49*	23	-.29	23
Duration until initiation of oral intake (days)	-.41	21	-.05	21
Duration until total oral intake achieved (days)	-.47*	20	-.11	20
Return to oral intake	-.36	23	-.45*	23
Mortality (death)	.06	23	.20	23

Note. * $p < .05$.

Severity of TBI on admission was significantly correlated with length of hospital stay and duration until total oral intake is achieved; therefore, participants who had more severe

head injuries were hospitalised for longer and took longer to achieve total oral intake.

Severity of TBI on admission was not significantly correlated with duration until initiation of oral intake, return to oral intake, and mortality. Furthermore, there was no significant association between TBI severity on admission and method of nutrition at discharge, $\chi^2(2, n = 25) = 5.16, p = .08$.

Severity of TBI at time of swallowing evaluation was significantly correlated with return to oral intake; therefore, participants with less severe head injuries were more likely to achieve oral nutrition again. Severity of TBI at time of SLP assessment was also significantly associated with method of nutritional intake at time of discharge, $\chi^2(2, n = 25) = 7.14, p = .03$: All 15 participants who had mild TBIs at time of SLP assessment were receiving nutrition orally at discharge, however, of the 10 participants with moderate TBIs at time of assessment, six (60%) were receiving altered oral diets and four (40%) were still receiving enteral feeds only. No participant had a severe TBI rating (as per GCS score) at the time of SLP assessment. TBI severity rankings at time of swallowing evaluation were not significantly correlated with any other health outcomes, namely, length of hospital stay, duration until initiation of oral intake and achievement of total oral intake, and mortality.

Type and duration of enteral nutrition. Table 9 shows associations between types of nutrition during hospital stay, specifically; oral nutrition, or enteral nutrition via nasogastric tube (NGT), or percutaneous endoscopic gastrostomy (PEG) and patient health outcomes.

Table 9

Associations Between Type of Nutrition During Hospital Stay and Health Outcomes for Participants With Dysphagia

Health outcomes	Oral intake, NGT, PEG
	χ^2_{ab}
Return to oral intake	13***
Method of nutrition at discharge (oral, NGT or PEG)	8.78**
Mortality	0.23

Note. ^a $n = 13$; ^b $df = 1$. ** $p < .01$; *** $p < .001$.

Type of nutrition during hospital stay is significantly associated with return to oral intake and method of nutrition at discharge: Within the study group, 13 participants received enteral nutrition during their hospital stay, three of whom had PEG tubes and 10 of whom had NGTs. All participants who had NGTs ($n = 10$) returned to oral intake and were receiving oral nutrition at discharge; however, all participants who had PEG tubes ($n = 3$) did not return to oral intake and were still receiving enteral nutrition via PEG at time of discharge (or just prior to death). No statistically significant association was identified between type of nutrition during hospital stay and mortality. This result is based on a small sample size ($n = 13$) and therefore, should be interpreted with caution.

Duration of enteral nutrition is positively and significantly correlated with length of hospital stay, $r(20) = .74, p < .001$, return to oral intake, $r_s(23) = .58, p = .002$, and mortality, $r_s(23) = -.49, p = .01$. Therefore, as duration of enteral nutrition increased, so did period of hospitalisation. Participants with long periods of enteral nutrition were also less likely to return to oral intake and had a greater likelihood of dying.

Respiratory status. Table 10 shows associations between respiratory status (requirement of ventilation, tracheostomy, or both) and patient health outcomes.

Table 10

Associations Between Respiratory Status and Health Outcomes for Participants With Dysphagia

Health outcomes	Ventilated, tracheotomised, or both
	χ^{2ab}
Return to oral intake	7.64*
Method of nutrition at discharge	8.12*
Mortality	6.52*

Note. ^a $n = 11$; ^b $df = 2$. * $p < .05$.

Respiratory status (requirement of ventilation, tracheostomy, or both) is significantly associated with mortality, return to oral intake, and method of nutrition at discharge: Six participants with dysphagia required ventilation, two required a tracheostomy, and three participants required both. All participants who had been ventilated ($n = 6$) returned to oral intake and were receiving oral nutrition at discharge. Participants who had been tracheotomised ($n = 2$) were still receiving enteral nutrition at discharge and had not returned to oral intake. Two of the three participants (67%) who had required ventilation as well as a tracheotomy were still receiving enteral nutrition and the other one participant (33%) was receiving oral nutrition at discharge. None of the participants that required either ventilation or a tracheostomy died; however, two (67%) of the three participants that required both, died.

Table 11 presents correlation results for participants' respiratory status and health outcomes.

Table 11

Correlations Between Respiratory Status and Health Outcomes for Participants With Dysphagia

Health outcomes	Ventilation		Days ventilated		Tracheotomy		Days with a tracheostomy	
	r_s	df	r	df	r_s	df	r	df
Length of hospital stay (days)	-.47*	23	.49*	20	-.67***	23	.60**	20
Duration until initiation of oral intake (days)	-.71***	21	.62**	20	-.32	21	.84***	20
Duration until total oral intake achieved (days)	-.80***	20	.58**	20	-.52*	20	.77***	20
	r_s	df	r_s	df	r_s	df	r_s	df
Return to oral intake	.02	23	.35	23	-.74***	23	.66***	23
Mortality	.24	23	-.23	23	.43*	23	-.27	23

Note. ** $p < .05$; *** $p < .01$; **** $p < .001$.

Ventilation and ventilation period were significantly correlated with length of hospital stay, duration until oral intake, and duration until total oral intake was achieved. Participants who required ventilation and had increased periods of ventilation were hospitalised for longer, took longer to initiate oral intake, and to achieve total oral intake. Ventilation was not significantly correlated with return to oral intake and mortality, however this result is based on a small sample size ($n = 9$) and should be interpreted with care.

Being tracheotomised was significantly correlated with period of hospitalisation, duration until total oral intake is achieved, return to oral intake, and mortality. Participants with tracheostomies were hospitalised for longer and took longer to achieve total oral intake than participants without tracheostomies. Tracheotomised participants were also less likely

to return to oral intake and had an increased likelihood of dying. Being tracheotomised was not significantly correlated with duration until initiation of oral intake.

Period of time with a tracheostomy is significantly correlated with period of hospitalisation, duration until initiation of oral intake, achievement of total oral intake, and return to oral intake. Participants who were tracheotomised for a longer period of time required longer periods of hospitalisation, took longer to initiate an oral diet, and achieve total oral intake, and were less likely to return to oral intake than participants without tracheostomies. Period of time with a tracheostomy was not significantly correlated with mortality.

Discussion

The incidence of TBI and prevalence of TBI-related dysphagia for adults in the Bloemfontein metropole, predictive factors for dysphagia, and relationships between severity of TBI, enteral nutrition, respiratory support, and patient health outcomes for patients with and without dysphagia are discussed. Information from relevant sections of the reported results has been integrated to create a coherent discussion. Recommendations regarding the management of patients with TBI and dysphagia are provided to guide SLPs and the multidisciplinary team.

The current study revealed that approximately 353 per 100,000 persons aged 18 to 68 years will sustain head injuries over the course of a year within the Mangaung Local Municipality, which has a population of approximately 747, 431 people (Statistics South Africa, 2011). Although the incidence rate was adjusted to account for the two hospitals that did not participate in the study, it should be noted that the calculated incidence of TBI may be an underestimate considering that only patients who were admitted to the hospital were included in the study.

Previous studies report varying incidence rates for TBI throughout the world ranging from 17.3 to 2710 per 100,000 (Andersson et al., 2003; Baldo et al., 2003; Emejulu et al., 2010; Firsching & Woischneck, 2001; Healthy People, 2010; Maset et al., 1993; Masson et al., 2001; Nell & Brown, 1991; Rickels et al., 2010; Santos et al., 2003; Servadei et al., 2002a; Servadei et al., 2002b; Shukri et al., 2006; Steudel et al., 2005; Yattoo & Tabish, 2008). Twenty-nine years ago Nell and Brown (1991) reported an incidence of 316 per 100,000 for persons between the ages of 15 and 64 years old in Johannesburg and Soweto in South Africa (Nell & Brown, 1991). The vast range in incidence rates world-wide can be attributed to variations in the age range of participants included in each study, period of time in which data was collected, study design, the communities' socio-economic statuses, and

population demographics, which makes comparison challenging (Seedat et al., 2009).

Twenty-nine years ago, Johannesburg and Soweto in South Africa had a very high incidence of TBI (Nell & Brown, 1991). The incidence rate of TBI in Bloemfontein, South Africa, is similar to the incidence rate for Johannesburg and Soweto reported by Nell and Brown (1991), which may suggest little progress in preventing the occurrence of TBI over the past three decades in South Africa.

In the present study, the primary mechanism for TBI in Bloemfontein was assault, accounting for 68% of head injuries. RTAs accounted for 23% (MVAs for 14% and PVAs for 9%), and miscellaneous accidents and falls each accounted for only 9% of TBIs. In a review of the literature, Bruns and Hauser (2003) reported that RTAs are the primary cause of TBI worldwide; however, Nell and Brown (1991) reported that assault and interpersonal violence were the primary mechanism for TBI in Johannesburg in 1986, accounting for 51% of TBIs for black South Africans and 10% for white South Africans, which is similar to the findings, regarding assault, from the current study. Norman and colleagues (2007) state that South Africa has a culture of violence that has resulted from the country's history of political unrest. Approximately two decades after *apartheid* it appears that inter-personal violence is still a major problem when results reported by Nell and Brown (1991), from a time of *apartheid*, are compared to the results from the present study. More recently, in the Free State, South Africa (the province in which Bloemfontein is situated) between 1997 and 2010, injury was the fourth leading cause of death after HIV, AIDS and tuberculosis, cardiovascular diseases, and cancers, accounting for 7.5% of mortalities (Msemburi et al., 2014). Intentional injuries and interpersonal violence accounted for close to half (43.3%) of these injuries (Msemburi et al., 2014), indicating that violence in South Africa continues to be problematic. Literature has suggested that various social and economic issues in South Africa, such as poverty, the high rate of unemployment, gender and income inequality, poor law regulation,

and substance and alcohol abuse have caused poor social cohesion and a breeding ground for interpersonal violence (Nell & Brown, 1991; Norman et al., 2007; Seedat et al., 2009).

Driving under the influence of alcohol, speeding or exhaustion while driving, and lack of safe walk ways for pedestrians have also been identified as causes of RTAs leading to injury and death in South Africa (Nell & Brown, 1991; Norman et al., 2007; Seedat et al., 2009).

The current study found that men are more at risk of sustaining TBIs than women (male-female ratio = 11.83:1). Ninety-two percent of the participants with TBI were male and only 8% of participants were female. In a review of the literature investigating the incidence of TBI, Bruns and Hauser (2003) also reported that world-wide, men are more at risk for TBI than women. Literature suggests that men are more likely to engage in behaviours that contribute to a higher incidence of TBI, such as carry and use weapons, competitiveness, take risks, and settling disagreements through physical violence (Bruns & Hauser, 2003; Seedat et al., 2009). This appears to be true for the Bloemfontein male population included in the current study where inter-personal violence was the leading cause of TBIs.

In the present study, the mean age of participants was 33.1 years. Similarly, Nell and Brown (1991) reported that the number of TBIs peaked in the 25 to 45 year age group (in Johannesburg, South Africa). Bruns and Hauser (2003) reported that the world-wide trend shows that incidence of TBI peaks for adolescents and young adults (approximately 15 to 25 years of age), which differs from that of South Africa as reported by Nell and Brown (1991) and the current study.

Intersectoral planning and TBI prevention education to reduce the occurrence of TBI among adult males is imperative in order to lighten the burden placed on the health care system by this population group (Norman et al., 2007). Norman and colleagues (2007) suggest that efforts for prevention of interpersonal violence and promotion of social cohesion

should be a multisectoral project, which may include media involvement, political participation for the development of policies and acts, and law enforcement to uphold the laws regarding assault, domestic abuse, drug use, driving under the influence of alcohol, and traffic rules. Prevention strategies employed in developed countries may not be appropriate for the South African context and further research may be needed to determine what is socially and culturally appropriate for a developing country like South Africa (Norman et al., 2007).

Thirty-two percent of all participants admitted with TBI presented with dysphagia in the present study. It should be noted that 49 patients (of a total of 164 patients) who were admitted to the participating hospitals were excluded from the study as they were unconscious, confused, not alert, or did not have capacity to provide informed consent due to the severity of their head injuries. A high prevalence of dysphagia in patients with severe TBI has been reported by several studies (Hansen et al., 2008; Mackay et al., 1999b). It is reasonable to surmise that a number of the patients excluded from the current study may have presented with dysphagia but were not identified. Therefore, the prevalence of dysphagia reported in this study is an underestimate of the number of patients who presented with dysphagia following TBI. It can thus be deduced that *at least* 1 in 3 persons admitted to the participating hospitals had dysphagia.

Previous studies reported prevalence rates for dysphagia ranging from 61% to 93% in adults with severe TBI (Hansen et al., 2008; Mackay et al., 1999a; Terré & Mearin, 2007). Researchers reported that aspiration occurred in 41% to 62.5% of patients with TBI-related dysphagia (Mackay et al., 1999a; Terré & Mearin, 2007). These studies (Hansen et al., 2008; Mackay et al., 1999a; Terré & Mearin, 2007) only included patients with severe head injuries in their research; however, the current study included all patients admitted with mild, moderate, and severe TBI, and excluded all patients who were confused or not alert (and as a

result, unable to provide informed consent to participate), which may account for the lower prevalence rate of dysphagia in the present study. Twenty-eight percent of participants in the present study who had swallowing difficulties also aspirated during clinical bedside evaluation, all of whom presented with severe TBI (as per GCS score). It should be noted that clinical bedside evaluation (which was employed for data collection in the present study) does not allow for the visualisation of the larynx and physiology of swallows, and so the prevalence of aspiration may have been underestimated as some participants may have silently aspirated, and thus, aspiration may have gone undetected (Terré & Mearin, 2007). Although direct comparisons cannot be made due to variations in research design, it is clear from the results of the current study that dysphagia and aspiration are common outcomes for patients who have sustained head injuries.

In the present study, all participants with normal swallowing were receiving an oral diet with no dietary restrictions (with SLP intervention) at time of discharge. Sixty-four percent of participants who presented with dysphagia at time of swallowing evaluation had achieved a normal oral diet prior to discharge, which is consistent with results reported in previous research (Hansen et al., 2008; Ward et al., 2007). Twenty percent of participants with dysphagia still required dietary modifications (8% required a soft diet and 12% required a liquid diet) at time of discharge and the remaining 16% of participants did not achieve oral intake and still required enteral nutrition prior to discharge. Although the majority of participants (64%) returned to oral intake, many participants (36%) still required dietary modifications and enteral nutrition at time of discharge. Participants with dysphagia took longer to initiate and achieve total oral intake and required enteral nutrition for longer periods of time than patients with normal swallowing (who may have required enteral nutrition while unconscious, due to decreased levels of consciousness, or cognitive difficulties). Mackay et al. (1999a) and Morgan et al. (2003) also reported that adult and paediatric patients with

TBI-related dysphagia took longer to initiate and achieve total oral intake than patients with normal swallowing. In the current study, participants with dysphagia also had significantly longer hospital stays and required more speech therapy sessions than those with normal swallowing, which could partly be owing to the fact that participants with difficulty swallowing required more time to achieve oral intake milestones before discharge from hospital. While there is no data available for adults, paediatric research (Morgan et al., 2003) also reported that patients with dysphagia following TBI had longer hospital stays and required speech therapy and enteral nutrition for a longer period of time than those with normal swallowing. It is recommended that hospitals ensure the availability of resources, such as NGTs, PEG tubes, and a variety of food consistencies to provide appropriate services and management for patients admitted with TBI and dysphagia. Human resources including SLPs for the assessment and management of swallowing (and speech, language, and cognitive-communicative difficulties) and dietitians for the management of individuals' nutritional needs may also be beneficial in the hospital setting. Patient discharge planning is necessary for patients who still require altered or enteral nutrition and out-patient SLP services to monitor and provide therapy for these individuals to ensure optimum outcomes. It is also recommended that patients and their caregivers be counselled regarding safe nutritional intake, how to prepare appropriate food consistencies (should the patient require an altered diet), and PEG tube hygiene and maintenance.

Age was the one variable that not associated with length of hospital stay, period of enteral nutrition, duration until oral intake and duration until total oral intake, suggesting that age does not influence health outcomes in patients with TBI who present with dysphagia. Mackay et al. (1999b) also reported that age did not have a significant relationship with duration until oral intake or total oral intake was achieved.

In the present study, the group of participants who presented with dysphagia had lower GCS scores than those with normal swallowing, indicating that dysphagia presented in cases with more severe TBI. Moreover, aspiration presented during assessment in all participants with severe TBI ($GCS \leq 8$). Further analysis showed that severe TBI ($GCS \leq 8$) is predictive of dysphagia. Previous adult studies have also reported that patients who present with dysphagia have lower GCS scores than those who have normal swallowing, which is consistent with results from the current study (Mackay et al., 1999a; Mackay et al., 1999b; Terré & Mearin, 2007). Morgan and colleagues (2003) reported that a GCS score lower than 8.5 is predictive of swallowing disorders in paediatric patients with TBI, which is similar to the findings from the current study where severe TBI ($GCS \leq 8$) is predictive of dysphagia in adults with TBI. It is thus recommended that patients who present with severe TBI at time of admission have an objective swallowing evaluation as soon as they are alert and medically stable to determine the presence of dysphagia. Although VFSS is the ideal method for objective assessment of dysphagia and aspiration (Costa, 2010), Fiberoptic Endoscopic Evaluation of Swallowing (FEES) may be considered for patients with TBI who cannot be easily transported and positioned for VFSS, and who are able to tolerate invasive procedures (Hiss & Postma, 2003). It should be noted that in the present study, although mild and moderate TBIs ($GCS = 9$ to 15) were not predictive of dysphagia, difficulty swallowing may still occur. It is therefore recommended that patients with mild to moderate TBIs be screened by an SLP for the early identification of swallowing disorders. Objective swallowing evaluation for patients with severe TBIs and screening of patients with mild and moderate TBIs for swallowing disorders may assist with referral for comprehensive assessment for detection and management of swallowing difficulties. Timely identification of dysphagia by an SLP may also allow for appropriate recommendations to be made for enteral or altered nutrition to ensure safe and appropriate nutritional intake to prevent

malnutrition and dehydration in patients with TBI (Mackay et al. 1999a; Morgan et al., 2003). Patients who present with dysphagia and aspiration are at risk for developing respiratory complications such as aspiration pneumonia, which could compromise their recovery or be life threatening (Clavé et al., 2006; Reilly & Ward, 2005). Patients with TBI are also at risk for malnutrition due to an increased caloric demand as a result of hypermetabolic reactions following TBI, which may be compounded by difficulty swallowing (Cook et al., 2008). Dénes (2004) reported that patients with TBI who are malnourished have difficulty mobilising, have more pressure sores, more contractures and surgeries for contractures, infections, and longer hospital stays than those who are adequately nourished. Adequate nutrition is essential for the recovery of patients with TBI and the management of hypermetabolic reactions leading to higher caloric demand (Cook et al., 2008; Dénes, 2004). Timely identification of dysphagia in patients with TBI and early initiation of therapy and nutritional management is therefore necessary to optimise nutrition and hydration and minimise the risks of aspiration pneumonia.

The present study showed that participants with dysphagia with low GCS scores at time of admission and at swallowing evaluation took longer to initiate oral nutrition and to achieve total oral intake than those with mild head injuries ($GCS \geq 13$). A low GCS score on admission and at time of swallowing evaluation was also associated with failure to return to oral intake prior to discharge. All participants with mild head injuries ($GCS \geq 13$) at time of swallowing evaluation achieved total oral intake and were receiving oral diets on discharge; however, only 60% of participants with dysphagia with moderate TBIs ($GCS = 9$ to 12) achieved total oral intake. The other 40% of participants with moderate head injuries were still receiving enteral nutrition at time of discharge. This indicates that patients with low GCS scores and thus, more severe head injuries, take longer than patients with mild head injuries to achieve oral intake milestones or will not achieve oral intake prior to discharge.

Ward and colleagues (2007) reported that adults with dysphagia with low GCS scores on admission took longer to begin oral intake and achieve total oral intake than patients with higher GCS scores. In the current study, low GCS scores (on admission) were associated with longer hospital stays, which may be because these individuals take longer to achieve oral intake milestones. Ward and colleagues (2007) also reported that patients with severe head injuries (GCS = 3 to 8) were hospitalised for significantly longer periods than patients with mild and moderate head injuries which is consistent with the findings from the present study. SLPs in hospitals may help to manage dysphagia and to shorten the hospital stays of patients with TBI-related dysphagia.

Type of enteral nutrition that participants received during hospital stay (NGT and PEG) was associated with type of nutrition at discharge (enteral or oral nutrition): All participants with dysphagia who were receiving nutrition via NGT during hospital stay returned to oral intake; however, all those who had PEG tubes were still receiving enteral nutrition (via PEG) at time of discharge. Nutrition via PEG was also associated with failure to return to oral intake prior to discharge. It is evident that patients who require PEG tubes for long term enteral nutrition during hospital stay are unlikely to achieve oral intake before discharge.

Participants with TBI who required enteral nutrition for an extended period of time via NGT or PEG had longer recovery periods than those with normal swallowing and were also more likely to die. The present study did not investigate the cause of death of patients who required long term enteral nutrition, but research suggests that early initiation of enteral nutrition (within the first 5 days of admission) significantly increases life expectancy of patients with TBI (Härtl, Gerber, Ni & Ghajar, 2008). Therefore, it is important that provision of nutritional intake is not delayed for patients with head injuries. Although the death of a patient may not always be preventable due to the extent of their injuries or due to

medical complications, the multidisciplinary team should closely monitor patients who require enteral nutrition for early identification of health risks that will compromise recovery or result in mortality, such as aspiration and aspiration pneumonia, poor tube maintenance and hygiene which may cause infection, and inadequate nutritional intake (Clavé et al., 2006; Dénes, 2004; Härtl et al., 2008).

Participants with swallowing disorders had significantly longer periods of ventilation than participants with normal swallowing; however, period of ventilation was not found to be predictive of dysphagia. Participants who required ventilation and who were ventilated for extended periods of time took longer to initiate and achieve total oral intake, and were hospitalised for longer than those who were not ventilated. Ventilation and period of ventilation did not influence mortality and return to oral intake prior to discharge. It is thus recommended that patients who require ventilation be referred to speech therapy for swallowing evaluation (when they are medically stable) for the early identification of dysphagia and initiation of in-patient dysphagia therapy to facilitate return to a full oral diet. In support of the current study, Mackay et al. (1999b) and Morgan et al. (2003) also reported that patients with dysphagia had significantly longer periods of ventilation than those without dysphagia. Both studies (Mackay et al., 1999b; Morgan et al., 2003) also reported that an increased ventilation period (more than two weeks for adults, and more than one and a half days for children) was predictive of dysphagia, which differs from the results of the present study. It should, however, be noted that Mackay and colleagues (1999b) warn that their results should be interpreted with care, as patients who had increased periods of ventilation also had lower GCS scores, which suggests that increased period of ventilation may be a result of more severe head injury, rather than period of ventilation. Patients with low GCS scores and dysphagia may therefore be compromised in terms of respiration and should be

monitored to ensure that no further respiratory complications occur that may compromise recovery and return to oral intake.

In the present study, tracheotomised participants had prolonged hospital stays, and took longer to achieve total oral intake than those who did not require a tracheostomy. Participants who required a tracheostomy for an extended period of time also had prolonged hospital stays and took longer to initiate and achieve total oral intake. The presence of a tracheostomy and period of time tracheotomised were also associated with failure to return to oral intake, in fact, all participants who had a tracheostomy failed to achieve an oral diet prior to discharge. Participants who had a tracheostomy had a greater likelihood of mortality; however, period of time with a tracheostomy was not associated with mortality. It is recommended that the respiration, nutrition and hydration of patients with tracheostomies are carefully managed and monitored and that return to oral intake be gradual to prevent further respiratory compromise (such as aspiration pneumonia), given the increased risk of mortality for these patients. Contrary to results obtained in the current study, Ward and colleagues (2007) reported that not having a tracheostomy was a risk factor for an increased period of time until total oral intake is achieved, but noted that this result may not be reliable as analysis was based on data from a small sample size ($n = 42$). Mackay and colleagues (1999a) reported that patients with tracheostomies took significantly longer to initiate oral intake and achieve total oral intake than patients without tracheostomies, which is consistent with the results from the current study.

Some participants from the present study required a tracheostomy as well as ventilation. Two thirds of the participants who were ventilated and tracheotomised did not achieve oral intake and thus, were still receiving enteral nutrition prior to discharge. Two thirds of the participants who required a tracheostomy and ventilation had also died while in the hospital. These patients appear to be more severely compromised in terms of respiration

and therefore more challenged with regard to return to safe oral intake. Prevention of further respiratory and health complications by preventing aspiration should be a priority. It is therefore recommended that oral intake be initiated by an SLP experienced in the field of dysphagia and when the patient is medically stable. It must be noted that these results should be interpreted with care, as they were based on small a small sample. Although GCS scores (on admission and SLP assessment) were not associated with mortality, other factors, such as polytrauma or internal injuries may have also contributed to mortality and even to failure to return to oral intake.

Epidemiological data from this study indicated that the incidence of TBI and prevalence of dysphagia in patients with head injuries is high, specifically in the young adult male population (male-female TBI incidence ratio = 11.83:1). Prevention programs to reduce the occurrence of TBI in this population are thus necessary. Currently, there are no best practice guidelines for the management of TBI-related dysphagia. Results from the current study provide SLPs and health care professionals with guidelines for the assessment and management of dysphagia in TBI patients in the hospital setting.

Recommendations that have been integrated into the discussion are summarised here. Patients with a GCS score of 8 or lower (severe TBI) should be objectively assessed for the detection of swallowing disorders and aspiration, as severe TBI was found to be predictive of dysphagia. Patients with mild or moderate head injuries (GCS = 9 to 15) should be screened for dysphagia, as although a GCS score of 9 to 15 is not predictive, swallowing disorders were still present in participants with mild and moderate TBIs. SLP intervention for patients who present with TBI-related dysphagia may help to manage dysphagia to improve patient outcomes. Patients who are unable to swallow safely or unable to meet nutritional requirements on an oral diet may benefit from enteral nutrition to ensure optimal nutritional intake. Ventilated and tracheotomised patients should be closely monitored by the

multidisciplinary team to ensure that respiratory status is not further compromised. Patient, family, and caregiver counselling is essential to ensure adequate continuation of care after discharge, at home or at a step down facility.

Study Limitations

This study aimed to determine the incidence of TBI, the prevalence of dysphagia in the Bloemfontein metropole, and compare health outcomes of patients with TBI with and without dysphagia; however, some limitations were encountered during the data collection process which may have affected the results.

Of the six hospitals in Bloemfontein which had trauma units or ICUs, only four hospitals agreed to take part in the study. An attempt was made to correct the incidence rate. Also, due to the nature of TBI, potential participants who were admitted to the participating hospitals had to be excluded as they were not capable of providing written informed consent. Some participants also died or were transferred to other hospitals before consent could be obtained or prior to swallowing evaluation and therefore, had to be excluded from the study. Only persons admitted to the hospital were included in the study. It is likely that individuals who sustained mild head injuries may not have sought hospital care and persons who sustained severe head injuries may have died prior to hospital admission. These individuals would not have been identified during the data collection process and were not included in epidemiological data. These factors may have lead to an underestimation of incidence of TBI and prevalence of dysphagia statistics in Bloemfontein, as well as patient outcome results.

All speech therapy sessions were counted and analysed, as opposed to dysphagia therapy sessions only. What was explicitly done during each therapy session was not available; therefore, therapy sessions to target speech, language, and cognitive-communicative difficulties were included in data analysis, which is not relevant to interpretations regarding need for dysphagia therapy.

Suggestions for Further Research

Studies reporting epidemiological data, specifically incidence of TBI and prevalence of dysphagia in South Africa are limited or outdated. It is recommended that epidemiological research be conducted on a larger scale in South Africa as incidence and causes of TBI may vary in different areas and communities. This epidemiological will contribute to health care planning and budgeting of resources for patients with TBI and dysphagia, and the understanding of design and implementation of targeted promotion and prevention programs to reduce TBI incidence (Cassidy et al., 2004; Reilly & Ward, 2005).

This study showed that assault and RTAs (MVAs and PVAs) account for a large percentage of TBI in Bloemfontein. The underlying causes of interpersonal violence and RTAs should be investigated for the purpose of preventing TBI in South Africa.

The current study also investigated the relationships between respiratory support and health outcomes in patients with TBI and dysphagia; however, results were based on a small sample size. It is recommended that further research be conducted regarding the impact of respiratory support to determine risk factors for poor health outcomes in patients who are ventilated and tracheotomised. This information will be valuable for SLPs and health professionals when planning management of patients with TBI, and counselling patients and their families.

Conclusion

The incidence of TBI in the Bloemfontein metropole is high compared to global standards. Men are also more at risk for TBI than women. The main mechanism for TBI in Bloemfontein was interpersonal violence, followed by RTAs. Prevention initiatives on a multisectoral level are necessary to reduce the number of TBIs due to assault and RTAs (Cassidy et al., 2004; Norman et al., 2007; Reilly & Ward, 2005), particularly among young adult males in the Bloemfontein metropole area. At least one third of patients who were admitted to hospital with TBI presented with dysphagia. Severe TBI ($GCS \leq 8$) was identified as a predictive factor for dysphagia. All patients with severe TBI at time of admission should have an objective swallowing evaluation as soon as they are medically stable. This will ensure timely identification of swallowing disorders and commencement of SLP intervention in order to reduce aspiration risk and improve oral intake. While not predictive, mild and moderate TBI severity also resulted in some cases with dysphagia and therefore, it is recommended that patients who present with mild to moderate TBIs be screened for dysphagia.

Participants with dysphagia had prolonged hospital stays, took longer to achieve oral intake milestones, and required more therapy than those without dysphagia. Participants with low GSC scores also had prolonged hospital stays, took longer to achieve oral intake milestones, and were less likely to achieve oral intake even with SLT intervention prior to discharge. Type of enteral nutrition during hospital stay is indicative of type of nutrition at discharge: All patients who had NGT tubes returned to oral intake; however, all patients who required PEG tubes did not achieve oral intake prior to discharge.

Patients who required respiratory support, such as ventilation or a tracheostomy, required longer hospital stays and took longer to achieve oral intake milestones. Period of ventilation was, however, not found to be predictive of dysphagia. An increased period of

time with a tracheostomy was associated with mortality. These results indicate that there is a need for enteral nutrition resources and supplements, which should be included in hospital and healthcare budgets, considering the high incidence of TBI and incidence of TBI. This information is also valuable for guiding health professionals for health care planning and when counselling patients, their families, and caregivers as what to expect regarding health outcomes and safe nutritional intake.

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Appendix A

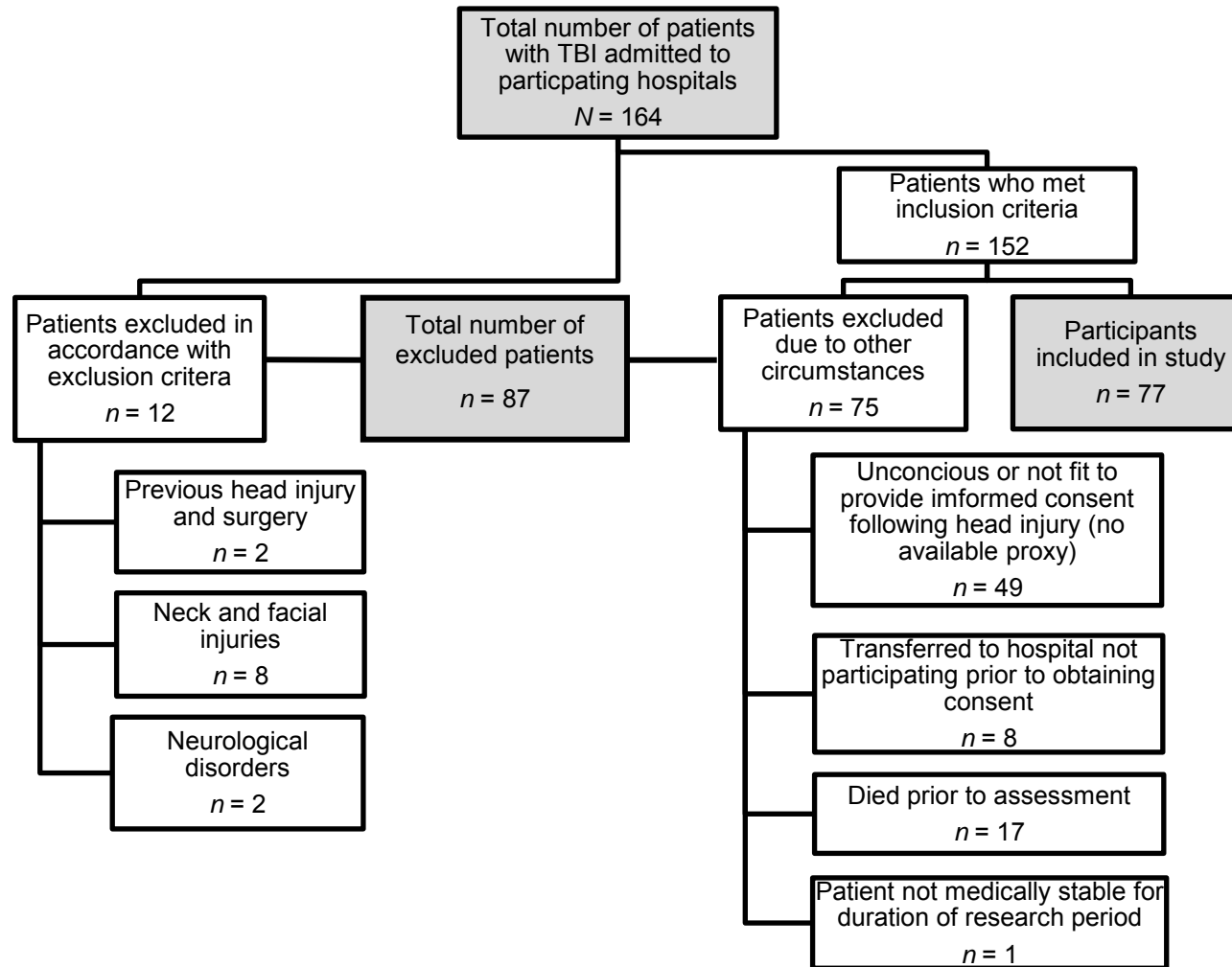


Figure 1. Recruitment process detailing inclusion and exclusion of participants.

Appendix B

Informal Screener for Determining Patients' Capacity to Provide Informed Consent

The capacity to give informed consent was determined by the following criteria and was assessed using the corresponding questions in Table 12 (Appelbaum, 2007; Grisso & Appelbaum, 1998).

Table 12

Criteria and Questions for Assessing Capacity to Give Informed Consent

Criteria	Questions
1 The patient is able to consistently indicate their choice to take part or not	“Would you like to take part in the research study?”
2 The patient understands the information provided	“What is the study about?” “What are the risks of taking part?” “What are the benefits of taking part?” “What will happen if you do not take part?”
3 The patient appreciates their medical condition or difficulty and the consequences of their management options	“What do you think is wrong with your health?”
4 The patient reasons by considering the risks and benefits of participation	“How did you decide to take part or not take part in this research study?”

Note. Adapted from “Assessment of patients' competence to consent to treatment,” by P. S.

Appelbaum, 2007, *New England Journal of Medicine*, 357, p. 1836. Copyright 2007 by

Massachusetts Medical Society., and “Assessing competence to consent to treatment: A guide

for physicians and other health professionals,” by T. Grisso and P.S. Appelbaum, 1998,

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Appendix C

Research Ethics Approval From the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee

UNIVERSITY OF CAPE TOWN



Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
e-mail: shuresta.thomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

23 August 2013

HREC REF: 502/2013

A/Prof S Singh
Health & Rehab
F45, OMB

Dear A/Prof Singh

PROJECT TITLE: PREVALENCE OF DYSPHAGIA AND FACTORS PREDICING HEALTH OUTCOMES FOLLOWING TRAUMATIC BRAIN INJURY IN ADULTS

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year till the 30th August 2014

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal Investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

Signature removed

PP
PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix D**Letter of Consent From Participating Private Hospitals to Conduct Research****RESEARCH OPERATIONAL COMMITTEE FINAL APPROVAL OF
RESEARCH**

Approval number: UNIV-2013-0029

Ms JC Rosewall

E mail: rosewalljoanne@gmail.com

Dear Ms Rosewall

**RE: PREVALENCE OF DYSPHAGIA AND FACTORS PREDICTING HEALTH
OUTCOMES FOLLOWING TRAUMATIC BRAIN INJURY IN ADULTS**

The above-mentioned research was reviewed by the Research Operational Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Private Hospital, has been approved, subject to the following:

- i) Research may now commence with this FINAL APPROVAL from the Committee.
- ii) All information with regards to Company will be treated as confidential.
- iii) Company's name will not be mentioned without written consent from the Committee.
- iv) All legal requirements with regards to patient rights and confidentiality will be complied with.
- v) Insurance will be provided and maintained for the duration of the research. This cover provided to the researcher must also protect both the staff and the hospital facility from potential liability
- vi) In accordance with MCC approval, that medicine will be administered by or under direction of the authorised Trialist
- vii) The research will be conducted in compliance with the GUIDELINES FOR GOOD PRACTICE IN THE CONDUCT OF CLINICAL TRIALS IN HUMAN PARTICIPANTS IN SOUTH AFRICA (2000)
- viii) Company must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

- ix) A copy of the research report will be provided to Company once it is finally approved by the tertiary institution, or once complete.
- x) Company has the right to implement any Best Practice recommendations from the research.
- xi) Company reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects/Netcare or should the researcher not comply with the conditions of approval.
- xii) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER.

We wish you success in your research.

Yours faithfully 


Prof [Redacted]
Full member - Research Operational Committee & Medical Practitioner evaluating research applications as per Company Policy


Chairperson, Research Operational Committee
Date:

This letter has been anonymised to ensure confidentiality in the research report.
The original letter is available with author of research

Letter of Consent From Participating State Hospitals to Conduct Research

28 August 2013

Me Joanne Rosewall
Dept. Occupational Health
[REDACTED] Hospital

Dear Me Rosewall,

RESEARCH PROJECT: PREVALENCE OF DYSPHAGIA AND FACTORS PREDICTING HEALTH OUTCOMES FOLLOWING TRAUMATIC BRAIN INJURIES IN ADULTS.

Herewith permission for the mentioned project to be done at [REDACTED] Hospital on the following conditions:

1. The research should not expose the users and the Department to any avoidable harm.
2. Annual progress reports should be submitted and also a research report at the end of the research process.
3. Reporting of Adverse Events related to the research process must be done within 48 hours of discovery.
4. There shall be provision for obtaining informed consent from all patients/staff where appropriate.
5. Briefing sessions should be conducted with all stakeholders prior to commencement and at the end of the study to provide feedback where appropriate.
6. That approval is obtained from the Ethics Committee.

The Chief Executive Officer must be notified if the findings of the project will be published and a research report needs to be sent to the Head Clinical Services as soon as the study is completed.

Yours sincerely

[REDACTED]

[REDACTED]

2013-08-28

HEAD: CLINICAL SERVICES

[REDACTED] HOSPITAL

HEAD: CLINICAL SERVICES: DR [REDACTED]
Private Bag [REDACTED] Bloemfontein, 9300. Tel. No.: [REDACTED]
Fax: [REDACTED] Room [REDACTED] Floor, [REDACTED] Hospital
Email: [REDACTED] gov.za

www.fs.gov.za



██████████ hospital
 Department of Health
 Hospital
 FREE STATE PROVINCE

INTERNAL MEMO

DATE:	28 AUGUST 2013	
TO:	Prof Singh S Healy and Rehab University of Cape Town Cape Town	FROM: Dr ██████████ Director: Clinical Services Tel: ██████████ ██████████

SUBJECT: PREVALENCE OF DYSPHAGIA AND FACTORS PRECIDING HEALTH OUTCOMES FOLLOWING TRAUMATIC BRAIN INJURY IN ADULTS
--

██████████ Hospital grants you permission if t he following criteria is met.

- That you obtain Ethical Clearance from the Human Research Ethics Committee of the relevant University.
- The Hospital incurs no cost in the course of your research.
- Access to the staff and patients at the ██████████ Hospital will not interrupt the daily provision of services.
- Prior to conducting the research you will liaise with the supervisors of the relevant sections and introduce yourself with permission letter and to make arrangements with them in a manner that is convenient to the sections.

Your Sincerely

██████████
 ██████████
 09-03-2013
 DEPARTMENT OF HEALTH

Director: Head Clinical Services