



# Management of civilian penetrating rectal injuries in an urban trauma centre

This thesis is presented for the degree of Master's in Medicine  
in General Surgery at the University of Cape Town

by

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## **Dedication**

*To my parents, Anba and Venilla, for their limitless love and support along this journey of Surgery.*

*To my wife and son, Amé and Alexander, for their patience, understanding and sacrifices they have made.*

*To Professor Navsaria, for his mentorship and guidance not only for this project but throughout my time here in Cape Town and for teaching me how to “operate” outside of the theatre.*

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## **Declaration**

I, Terron Govender hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature: Dr Terron Govender .....

Date: 24.03.2024

# Abstract

## **Background:**

Rectal injuries are associated with significant morbidity. Primary repair of extraperitoneal rectal injuries, presacral drainage (PSD) and distal rectal washout (DRW) have become historical adjuncts.

## **Aim:**

A retrospective review was performed to determine the outcome of rectal injuries in an urban trauma centre with a high incidence of penetrating trauma where a simple surgical management approach to these injuries is practiced.

## **Methods:**

The records of all patients with a full-thickness penetrating rectal injury admitted to the Trauma Centre at Groote Schuur Hospital over a 10-year period (January 2010 – December 2019) were reviewed. Basic demographics, injury mechanism and perioperative management, anatomical site of the rectal injury, associated intra-abdominal injuries and their management were recorded. Infectious complications and mortality were noted. Intraperitoneal rectal injuries were primarily repaired, with or without faecal diversion. Extraperitoneal rectal injuries were generally left untouched, and a diverting loop colostomy done. Intraperitoneal bladder injuries were primarily repaired and extraperitoneal bladder injuries were repaired from within the bladder. Pelvic and spinal fractures were copiously lavaged. Presacral drainage and DRW were not performed.

## **Results:**

One-hundred and four (101: gunshot; 3: stab) patients with 134 rectal injuries [intraperitoneal (10), extraperitoneal (64), combined (30)] were identified. Transpelvic trajectory was identified in 75 (72.12%) patients. Associated genitourinary tract injuries occurred in 42 (40.38%) patients and included 27 (25.96%) bladder injuries [intraperitoneal (9), extraperitoneal (4), combined (14)] and seven (6.73%) distal ureter injuries. Fifty patients

(48.08%) had associated bony injuries: sacrum (22), iliac (9), pubic rami (5), coccyx (1), acetabulum (3), femur (6), vertebral fractures (3) and pelvic joints (5). Eight (7.69%) patients had an associated vascular injury [iliac veins (4), iliac arteries (4)]. Two extraperitoneal rectal injuries were repaired. Diverting loop colostomies (91) and three Hartmann's type procedures were done for the remaining untouched extraperitoneal rectal injuries. None had PSD or DRW. Nine (6.7%) fistulae were recorded: three rectocutaneous, three rectovesical, one small bowel cutaneous, one vesicocutaneous and one entero-enteric. There were 27 infectious complications: surgical site infection (13), iliac blade and sacral osteitis (2), other soft tissue infections (12).

### **Conclusion:**

Extraperitoneal rectal injuries due to low-velocity trauma can be safely managed by faecal diversion, without repair, DRW and PSD with minimal morbidity.

**Keywords:** *penetrating trauma, rectal injury, bladder injury, extraperitoneal, intraperitoneal*

# Publication Ready Manuscript

## Management of Civilian Penetrating Rectal Injuries in an Urban Trauma Centre

The management of penetrating civilian rectal injuries has evolved from the cumbersome military surgical dogma of the four D's – debridement, diversion, drainage and distal washout which found its way into civilian practice, to the more recent well reported minimalist approach to extraperitoneal rectal injuries with diversion alone, with equal or better results.(1)(2)(3). The rectum, with its unique relation to the peritoneal surface coupled with the complicated anatomy of the narrow pelvis and its associated vital structures, provides a maze for the surgeon to navigate in the traumatised patient. Combined with the infrequency of rectal injury occurrence, these injuries can aptly be described as uncharted territory for many surgeons. Consequently, an optimal management strategy is required to guide the surgeon treating these injuries. The aim of this study was to review the experience with rectal injuries of a single centre with high volumes of penetrating trauma and to determine outcomes with regards to fistulae and infectious complications.

### Methods

This was a retrospective study which included all patients who sustained a penetrating rectal injury between 01 January 2010 and 31 December 2019 (10-years). Patients who died prior to management of a rectal injury or those who underwent a damage control procedure were excluded. The names of patients with rectal injuries were retrieved and cross-referenced from the following existing databases; Groote Schuur Hospital Trauma Centre electronic health record, Groote Schuur Hospital Trauma Centre T6 electronic health record, and the Department of Stoma Therapy records of stomas performed for rectal injuries. Patient folders were reviewed and the following data extracted: *demographics, mechanism of injury (gunshot wound or stab), admission physiology, injury severity scores (ISS – Injury Severity Score, PATI – Penetrating Abdominal Trauma Index; RTS – Revised Trauma Score and TRISS – Trauma and Injury Severity Score); location of rectal injury (intraperitoneal or extraperitoneal), associated injuries (including urinary tract and orthopaedic injuries),*

*diagnostic tests, management of rectal injury (no repair, direct repair, proximal diversion, distal rectal washout, presacral drain), hospital and ICU stays, complications and mortality.*

All patients were managed along ATLS<sup>®</sup> guidelines and previously published institutional algorithm(1). All patients with a missile trajectory in the vicinity of the pelvis underwent digital rectal (DRE) and proctosigmoidoscopic examination. Patients that were haemodynamically unstable or with signs of frank peritonism underwent emergent exploratory laparotomy. Intraperitoneal rectal injuries were primarily repaired, with or without fecal diversion. Extraperitoneal rectal injuries were generally left untouched, and a diverting sigmoid loop colostomy done. A highly select group of patients with a suspected isolated extraperitoneal rectal injury with either no clinical evidence of acute peritonitis, or equivocal abdominal signs, underwent a diagnostic laparoscopy. Those patients whose laparoscopic examinations were normal, had a sigmoid loop colostomy fashioned in the left iliac fossa through an abdominal wall trephine approach without laparotomy. Presacral drainage and DRW were not routinely performed (See Figure 3). Patients with haematuria were investigated when there were no indications for urgent laparotomy. Those patients with associated bladder injuries were managed as per location: intraperitoneal bladder injuries were repaired primarily; extraperitoneal bladder injuries were managed via cystotomy and repair from within the bladder. All fractures and joint injuries were lavaged. Amoxicillin and clavulanic acid was routinely administered for five days in patients with an extraperitoneal injury which was not repaired. Colostomy closure was planned for 3 months from the time of discharge. Prior to closure, all patients underwent digital rectal examination to evaluate sphincter function, and a barium contrast enema to exclude any stricture or fistula formation.

All data was compiled in a spreadsheet authoring software Numbers for Macintosh OS to allow for analysis.

## **Results**

For the period under review (January 2010 to December 2019), 110 patients sustained a rectal injury, six of whom had a damage control laparotomy and were excluded. Of the remaining 104 patients, male gender predominated with 97 patients with a mean age of 28.40 (15-56 years). Gunshot wounds were the leading cause of injury in 101 patients. Three patients sustained stab wounds. A transpelvic (between iliac crests and perineum) trajectory (4) was

noted in 75 (72,12%) patients. Other trajectories resulting in RI accounted for the remaining 29 cases (27,88%) (See Table I).

<b>n = 104</b>	
Gender	Female: 7 Male: 97
Age	28.40 (IQR 13) years
Mechanism of Injury	GSW: 101 Stab: 3
Trajectory	Transpelvic: 75 Other: 29
Evidence of shock on presentation	12 (11.54%)
Peritonism on presentation	65 (62.50%)
Trauma Scores	
ISS	19.02 (IQR 5)
PATI	19.59 (IQR 11)
RTS	8.23 (IQR 0)
TRISS (Penetrating)	99.90 (IQR 0.0385)

Table I: Patient Demographics and Injury Characteristics

At presentation, 12 (11.54%) patients had evidence of haemorrhagic shock and responded to simple resuscitation. Sixty-five (62.50%) patients presented with peritonism on abdominal examination. Digital rectal examinations (DRE) were performed in 100 patients and 55 yielded blood on the glove. Rigid sigmoidoscopy (RS) was performed in 100 patients in the preoperative period. Of the 100 RS, 96 (96.0%) yielded a positive result based on the presence of blood or detection of a rectal injury. Haematuria was present in 65 patients (62.5%), 41 and 24 patients with microscopic and macroscopic haematuria, respectively. Contemporary Trauma Scoring Systems were calculated, and the results are reflected in Table I.

Of the 104 patients in the primary analysis, 134 rectal injuries (RI) were identified: 10 intraperitoneal (IP), 64 extraperitoneal (EP) and 30 combined (IP and EP). Eighty-nine loop sigmoid colostomies were performed for extraperitoneal rectal injuries. Thirty intraperitoneal rectal injuries were managed with primary repair alone (Fig 1). A summary of all procedures

performed for RI can be found in Table II. No patients underwent presacral drainage or distal rectal washouts.

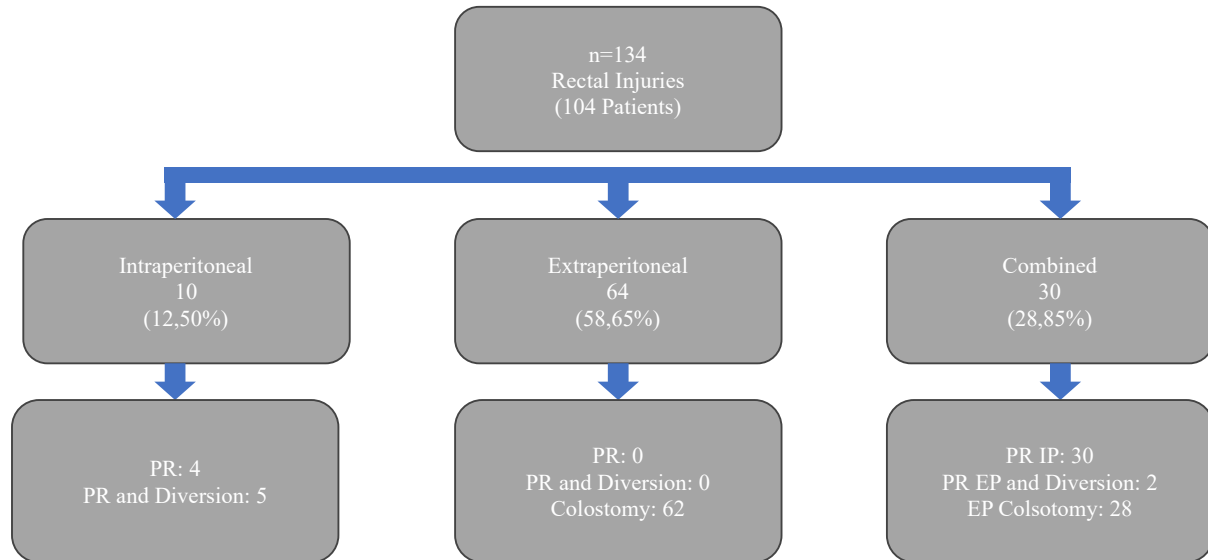


Figure 1: Overview of Rectal Injuries and their Management

PR: Primary Repair

IP: Intra-peritoneal

EP Extra-peritoneal

<b>n=134</b>	
<b>Extra-peritoneal Rectal Injuries (94)</b>	
Loop Sigmoid Colostomy	84
Laparoscopic Assisted Loop Sigmoid Colostomy	4
Loop Colostomy in different position	1
Primary Repair and Loop Sigmoid Colostomy	2
Hartmann's Type Procedure	3
<b>Intra-peritoneal Rectal Injuries (40)</b>	
Primary Repair	30
Primary Repair and Loop Sigmoid Colostomy	9
Hartmann's Type Procedure	1

Table II: Procedures Performed for Rectal Injuries

Associated lower urinary tract injuries were present in 42 (40.38%) patients and included 27 (25.96%) bladder injuries of which there were nine intra-peritoneal, four extra-peritoneal, 14 combined intra- and extra-peritoneal injuries. See Figure 2 for a summary of concomitant

bladder injuries and their management. Other associated abdominal injuries are listed in Table III.

Presumptive empiric antibiotic therapy was administered to all patients. Fifty-one (49.03%) received amoxicillin and clavulanic acid, 42 (40.38%) had received triple therapy which consisted of ampicillin, gentamycin and metronidazole. Ten (9.62%) patients received clindamycin and ciprofloxacin and one (0.96%) patient received ceftriaxone and metronidazole.

Surgical site infections occurred in 13 (12.50%) patients: six were superficial and four were deep. Organ space / intra-abdominal infections occurred in three (2.88%) patients. Twelve (11.54%) patients complicated with soft tissue infections as listed in Table IV. The complicated soft tissue infections (abscess collections and necrotising fasciitis) had occurred in association with a bullet trajectory that had passed through the rectum. Nine (8.65%) patients developed fistulae: three were recto-cutaneous, three were recto-vesical, one vesico-cutaneous, one entero-cutaneous and one entero-enteric (see table IV).

Ninety-one (%) colostomies were performed for EPRI. During the study period, 67 of these were reversed. Significant complications include surgical site infections (of the closed ostomy site – 2 patients), bowel obstruction (3 patients), anastomotic leak (1 patient), fistula – colocutaneous (1 patient) and stoma site hernia (1 patient). These findings as well as managements are expanded on in Table V.

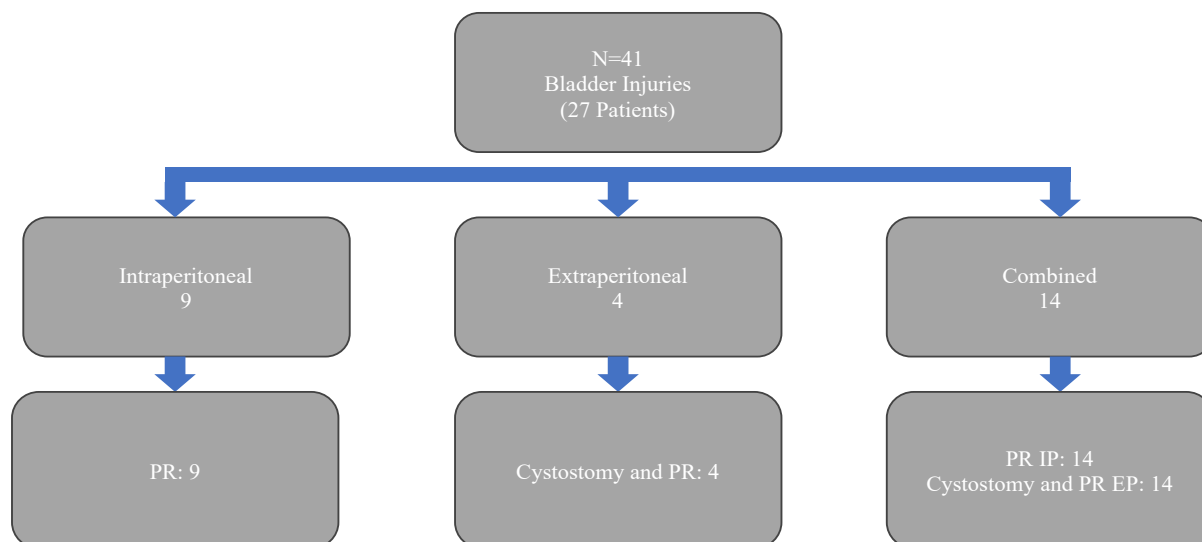


Figure 2: Overview of Associated Bladder Injuries and their Management  
 PR: Primary Repair  
 IP: Intra-peritoneal  
 EP Extra-peritoneal

	No. of patients (%)	
Small Bowel	52	(50,00)
Large Bowel	17	(16,35)
Genitourinary Tract	42	(40,38)
Kidney	3	(2,88)
Ureter	7	(6,73)
Bladder	27	(25,96)
Intra-peritoneal	9	(8,65)
Extra-peritoneal	4	(3,85)
Combined	14	(13,46)
Urethra	2	(1,92)
Genitalia	3	(2,88)
Bone and Joint Space	50	(48,08)
Sacrum	22	(21,15)
Coccyx	1	(0,96)
Vertebra	3	(2,88)
Iliac	9	(8,65)
Pubic Rami	5	(4,81)
Acetabulum	3	(2,88)
Femur	6	(5,77)
Pelvic Joints	5	(4,81)
Vascular	8	(7,69)
External Iliac Vein	2	(1,92)
Internal Iliac Vein	2	(1,92)
External Iliac Artery	2	(1,92)
Internal Iliac Artery	2	(1,92)

Table III: Associated intraabdominal injuries

		Patients
Surgical Site Infection		13
Surgical Site Infection - Superficial	6	
Surgical Site Infection - Deep	4	
Intra-Abdominal Collection	3	
Soft Tissue Infections		12
Abscess	2	
Necrotizing Fasciitis	2	
Pre Sacral Collection	3	
Bullet Tract Infections	5	
Fistulae		9
Recto-Cutaneous	3	
Recto-Vesical	3	
Vesico-Cutaneous	1	
Entero-Cutaneous	1	
Entero-Enteric	1	
Osteitis		2

Table IV: Complications

Number of stomas		94
Type	Refer to Table II	
Number of stomas reversed		67
Preoperative loopogram		75
Normal study	74	
Rectovesical Fistula	1	
Complications after reversal		9
Surgical Site Infection - Superficial	2	
Bowel Obstruction	3	
Small Bowel	2 - Conservative management	
Large Bowel	1 - Take down and Hartmanns Procedure	
Anastomotic Leak	1 - Take down and Hartmanns Procedure	
Fistula - Colocutaneous	1 - Conservative management	
Stoma Site Hernia	1	

Table V: Colostomy outcome in extraperitoneal rectal injury

## Discussion

To comprehend the complexity of a rectal injury, one must be familiar with the normal rectal anatomy. The rectum is a tubular structure of the large bowel measuring approximately 12-15cm in length. It originates as a continuation of the sigmoid colon and terminates at the anal canal. The peritoneal reflections surrounding the rectum are not complete. The proximal third of the rectum is covered anteriorly and laterally by peritoneum, the middle third is covered

anteriorly and the distal third is completely extraperitoneal. This leads to a crucial anatomical distinction which prompts surgical management decisions. Furthermore, the rectum is devoid of a mesentery and is instead enveloped by the visceral pelvic fascia.(5)

Rectal injuries are a rare occurrence. A retrospective review reported an incidence of 0.1% in the United States population.(6) In two separate series covering penetrating rectal injuries by Navsaria et al, the authors had documented 104 patients over a two year period(7) and 92 patients over 4 years.(1)

Penetrating trauma has traditionally accounted for the majority of rectal injury and specifically low velocity firearms in the civilian setting. Review of contemporary data sets confirms this to still hold true.(6)(8)(9) Locally a recent review in 2020, found 80% of RI were due to penetrating mechanisms, 14% were due to blunt mechanisms and the remaining 6% were attributable to both penetrating and blunt trauma. 71% of the penetrating trauma were due to firearm injury.(2)

Conventionally, RI are classified on the mechanism of injury – penetrating or blunt, as outlined above, and more practically on the anatomic relation of the injury to the peritoneal cavity. Extraperitoneal rectal injury (EPRI) are injuries which do not communicate with the peritoneal cavity. Intraperitoneal rectal injury (IPRI) are those that communicate with the peritoneal cavity proper and combined injuries (CI) are combinations of the two.

With the low incidence of occurrence and lack of hard clinical signs the EPRI remains a difficult diagnosis to achieve with devastating consequences when delays occur. DRE and RS, despite their accuracy in non-benign lesions of the rectum, have low sensitivities in detecting RI - 51% and 78%, as reported by Hargreaves et al.(10) For this reason, early identification should begin with recognition of patients sustaining a transpelvic trajectory in penetrating trauma and patients without indications for expedited laparotomy should undergo cross sectional imaging to establish tracts and associated injuries. This further highlights the need for an algorithmic and standardized approach in managing these patients.

The contemporary management of RI has been largely consolidated on the following principals – IPRI can be managed with primary repair, EPRI are best managed with diversion. PSD and DRW have had periods of being in vogue, however, the true benefit of these cumbersome adjuncts has never been described emphatically. Proponents for and against their routine use have, ultimately, demonstrated the same outcomes in regard to morbidity and mortality.(11)(12)(13)(14)(15)(16)(17) In our practice we have found the algorithm(1) (see Figure 3) proposed by Navsaria et al to hold true and simplify the management of RI, with the current series solidifying this. In our view routine DRW and PSD have no role in contemporary management of RI. Drainage should be limited to those patients with delayed presentation of RI and established infectious complications in the pelvis and soft tissues. Furthermore, DRW and PSD has been shown to be independent risk factors for developing intraabdominal sepsis.(8)

Given the intimate relationship between the urogenital tract, pelvic organs and rectum, associated injuries and their management should be of high concern. The bladder with its relation to the peritoneal surface is also subjected to both extra peritoneal and intraperitoneal injuries. Our data shows a high frequency of associated genitourinary tract (40,38%) and bone and joint space injuries (48,08%). Earlier literature reviewing the association, established a frequency rate of associated genitourinary tract injuries at 41,3%.(18) A more recent large multicentre review of rectal and associated genitourinary tract injuries reported a frequency rate of 42%.(19) This is in keeping with our own data (see Table III). Our approach to managing bladder injuries has been outlined above. Given the low frequency of complications (see Table IV) it would be fair to assume that IP bladder injuries can be managed with primary repair and EP bladder injuries can be managed via cystostomy and repair from within the bladder with no need for suture line separation from the repaired or unrepaired rectal injury, with minimal sequelae.

Bone and joint space injuries are also commonly associated with penetrating RI.(8)(9) Our series here demonstrated nearly half (48,08%) of the patients had an associated bone injury. The injuries were thoroughly washed out after managing the other injuries in theatre. Only 2 patients complicated with an osteitis. Given this finding it would be fair to assume this management is appropriate. Identifying trajectories would potentially help stratify those patients with an increased risk of bone complications if the tract were established to have

entered the rectum first. Empiric antibiotic therapy with amoxicillin and clavulanic acid would be regarded as appropriate. The small portion of patients who received clindamycin and ciprofloxacin were those treated during a period where empiric therapy in GSW and bone fractures were treated as such. This was based on the hospital antibiotic policy at the time. The current policy is of amoxicillin and clavulanic Acid for 5 days for all patients with unrepaired rectal injuries with or without associated bone injuries.

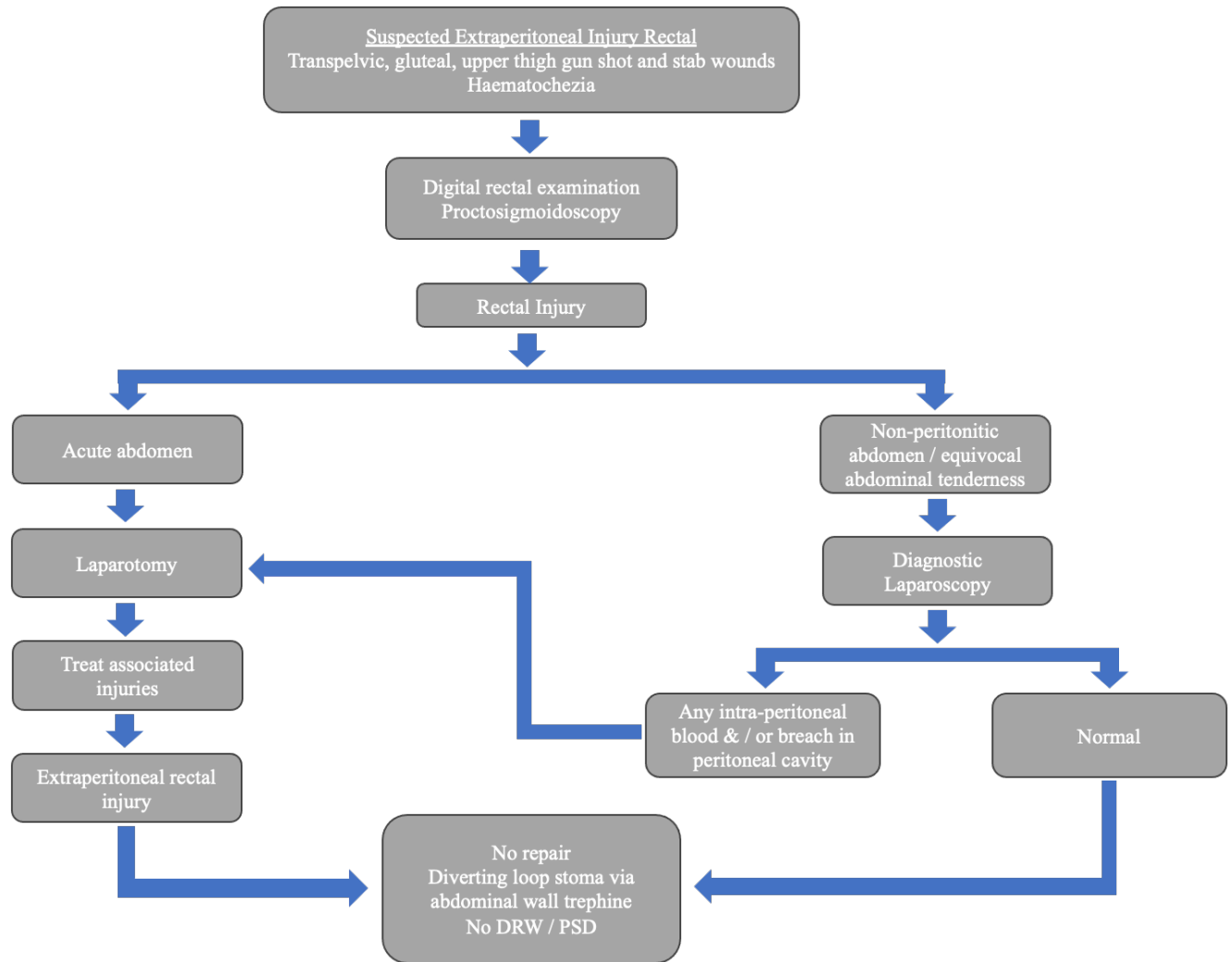


Figure 3: Management algorithm for low velocity penetrating extraperitoneal rectal injuries. Reproduced from Navsaria et al.(1)

	Period (years)	n	Penetrating Mechanism (%)	EPRI (%)	EPR Repair (%)	DRW (%)	PSD (%)	PS(%)	RF (%)
Trunkey et al., 1973	10	45	44 (98)	a	a, b	a	45 (100)	0	0
Tuggle and Huber, 1984	9	47	46 (98)	a	19 (40) d	1 (2)	45 (95)	1 (2)	3 (6)
Mangiante et al., 1986	15	43	43 (100)	12 (30)	d	40 (93)	21 (43)	4 (9)	0
Burch et al. 1989	10	100	95 (95)	100 (100)	21 (21)	46 (46)	93 (93)	4 (4)	3 (3)
Thomas et al., 1990	8,5	52	50 (96)	?37 (71)	3 (8)	26 (50)	35 (67)	0	0
Ivatury et al., 1991	14	51	51 (100)	?42	17 (4)	22 (43)	43 (84)	3 (5)	1 (2)
Bostic and Johnson, 1993	2,8	28	28 (100)	28 (100)	9 (32)	13 (46)	25 (89)	1 (4)	0
Levy et al., 1995	1,6	26	26 (100)	26 (100)	10 (38)	16 (42)	12 (46)	6 (24)	2 (8)
Levine et al., 1996	4	30	26 (87)	30 (100)	3 (10)	10 (67)	22 (73)	1 (3)	1 (3)
Steinig and Boyd, 1996	10	22	22 (100)	22 (100)	5 (23) e	12 (60)	8 (40)	0	0
Gonzales et al., 1998	3,7	48	48 (100)	48 (100)	a	0	23 (48)	3 (6)	1 (2) f
McGrath et al., 1998	5	58	58 (100)	42 (72)	4 (10)	33 (87)	30 (79)	3 (8)	0
Morken et al., 1999	10	45	38 (84)	a	21 (46) g	24 (53)	12 (26)	2 (4)	0
Velmahos et al., 2000	4	30	30 (100)	30 (100)	12 (40)	0	6 (20)	1 (3)	2 (6)
Navsaria et al., 2001	5	10	9 (90)	10 (100)	0	2 (20)	0	0	0
Navsaria et al., 2004	5	20	20 (100)	20	0	0	0	0	2 (10)
Weinberg et al., 2006	5	54	54 (100)	50 (92)	11 (22)	0	38 (70)	0	0
Navsaria et al., 2007	4	92	92 (100)	85 (92)	2 (2)	2 (2)	0	0	2 (2)
Gümüs et al, 2011	10	29	29 (100)	19 (66)	4 (17)	a	a	1 (3)	3
Savoie et al, 2017	10	62	53 (86%)	27 (51)	a	13 (21)	11	4	a
Uchino et al, 2020	6,5	51	41 (80)	31 (61)	0	a	1 (2)	15 (29)	a
Govender et al (Present Series)	10	104	104 (100)	94 (70)	2 (2)	0 (0)	0 (0)	10 (12)	6 (6)

Table VI: Select publications with more than 80% penetrating mechanism over the preceding 5 decades. Adapted from Navsaria et al.(1)

EPRI - Extraperitoneal rectum, DRW - distal rectal washout, PSD - presacral drainage, PS - Pelvic Sepsis, RF - Rectal Fistula

a - not stated

b - 'Repaired when feasible'

c - Rectal injuries repaired in 19 patients

d - So few' amenable to closure'

e - Five had debridement

f - Related to foreign body with 'resolution of fistulous tract following missile removal'

g - Damage repair

It would be worthy to note that though the infection risk appears to be high, a fair portion of patients sustained concurrent injuries to other organs and presented with overt peritonism. The complications relating to management of RI should be viewed in terms of skin infections and fistulae alone (see Table IV).

## **Conclusion**

Our results support the low incidence of RI. There is no consensus regarding the optimal management, however, based on the low complication rate we suggest that safe management of RI includes the following; EP RI can be safely managed by diversion alone, non-destructive IP RI can be primarily repaired, concurrent injuries to the genitourinary tract can be managed without the need for suture line separation of repaired bladder injuries, associated bone injuries should undergo a formal washout if the trajectory of the missile passes through bowel prior to the bone. Further empiric treatment with amoxicillin and clavulanic acid appears to be appropriate.

An inference of social importance can also be made. Previous publications from the same institution reported on a higher incidence in a shorter time frames.(1)(7) With rising numbers of interpersonal violence in the city as well as throughout the country coupled with increasing mortalities associated with firearm injury(20), two possibilities can be entertained. First the availability of firearms and munitions has drastically increased and second the proficiency for more lethal shots has increased. Calls for government to increase and direct the policing efforts towards this avenue should be considered. This could be aided with stricter gun control laws and increasing the efforts to eradicate illegal firearms.

## **Limitations**

Due to the retrospective nature of this study it will have its inherent biases and constraints.

As this is a teaching facility the rotating surgical trainees result in heterogeneity in subjective aspects such as RS and identifying the injury location and technical aspects surrounding surgical skill set.

Majority of the RS performed failed to identify an exact location of injury, but this is not out of keeping with other reported datasets in published literature.

### **Conflict of interest**

The authors declare no conflict of interest.

### **Funding source**

No funding was required.

### **Ethical approval**

This study was approved by the University of Cape Town Human Research Ethics Committee (HREC) as part of completion of the MMed of Dr Terron Govender on 28.02.2021 HREC 467/2018

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# Appendix

## HREC Approval



UNIVERSITY OF CAPE TOWN  
Faculty of Health Sciences  
Human Research Ethics Committee



Room E53-46 Old Main Building  
Grootes Schuur Hospital  
Observatory 7925  
Telephone [021] 406 6626  
Email: [shuretta.thomas@uct.ac.za](mailto:shuretta.thomas@uct.ac.za)  
Website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)

25 July 2018

**HREC REF: 467/2018**

**Prof P Navsaria**  
Department of Surgery  
Trauma Centre, C14, NGS

Dear Prof Navsaria

**PROJECT TITLE: MANAGEMENT OF CIVILIAN PENETRATING RECTAL INJURIES IN AN URBAN TRAUMA CENTRE**

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

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

**Approval is granted for one year until the 30 July 2019.**

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/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms))

**Please quote the HREC REF in all your correspondence.**

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

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

*Yours sincerely*

**PROFESSOR M. BLOCKMAN**  
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**

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), South African Good Clinical Practice Guidelines (DoH)

# HREC Renewal



## FHS016: Annual Progress Report / Renewal

<b>HREC office use only (FWA00001637; IRB00001938)</b>			
This serves as notification of annual approval, including any documentation described below.			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	28.02.22
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	24/2/24

Note: Please note that incomplete submissions will not be reviewed.  
Please email this form and supporting documents (if applicable) in a combined pdf-file to [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za).  
Please clarify your plan for research-related activities during COVID-19 lockdown

Comments to PI from the HREC

### Principal Investigator to complete the following:

#### 1. Protocol information

Date (when submitting this form)	21.02.2021		
HREC REF Number	467/2018	Current Ethics Approval was granted until	30.07.2019
Protocol title	Management of Civilian Penetrating Rectal Injuries in an Urban Trauma Centre		
Protocol number (if applicable)	Project 2018/090		
Are there any sub-studies linked to this study?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.	N/A		
Principal Investigator	PH Navsaria		



## **Conflict of Interest Statement**

Date: 30.03.2024

To whom it concerns

Management of Civilian Penetrating Rectal Injuries in an Urban Trauma Centre

Conflict of Interest Statement

I declare no conflict of interest in preparation or subsequent publication of this material.

Yours sincerely,

Terron Govender

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Cape Town, South Africa

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