Informed consent for peripheral nerve blocks at a tertiary level hospital in South Africa: A quality improvement project

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Abstract

Background

In South Africa, the doctrine of informed consent, introduced by the South African courts (Cape Provincial Division), dictates that all reasonable patients (the reasonable patient standard requires that a patient be told of all material risks that would influence a reasonable person in determining whether or not to consent to the treatment) be told of material risks and alternative options before consenting to medical treatment or procedural interventions. Regional anaesthesia, including peripheral nerve blocks (PNBs), provides a plethora of benefits to patients undergoing surgery but, due to potential risks involved, also requires informed consent. Studies have shown that South African anaesthetists do not regularly obtain adequate informed consent for these procedures. We implemented a quality improvement project to facilitate and enhance documented informed consent in our setting.

Methods

A prospective quality improvement project was established at Groote Schuur Hospital, Cape Town, including all PNBs performed in two-week blocks before and after the introduction of a standardised regional anaesthesia informed consent form. The primary outcome, comparing the incidence of documented informed consent between the two groups, was assessed with the McNemar paired-sample test for differences in proportions. Regression analysis was used to explore the effect of prespecified confounders (documented consent taken; benefits discussed; alternatives discussed; complications discussed and whether autonomy was documented).

Results

Thirty-nine and forty-three patients were included in the pre- and post-intervention groups, respectively. In our setting, anaesthetists were 4.16 (95% confidence interval (CI) -6.67 to -2.98, $p<0.001$) times more likely to take documented informed consent when provided with a standardised form. The incidence of documented informed consent improved from 7.7% to 60.5%. Regression analysis showed that these confounders influenced the recall of the PNB consent and discussed benefits and complications. Overall, recall was mostly influenced when benefits were discussed with patients (95% CI -20.023 to -14.64, $p<0.001$).

Conclusion

Documentation of informed consent for PNBs in our setting is poor. A standardised consent form can facilitate the documentation of consent significantly. Patient recollection of the consent process also improved, specifically when benefits were discussed.

Keywords: informed consent, documentation, peripheral nerve blocks

Background

The HPCSA guidelines on informed consent reference Section 6(1)(b) & (c) of the National Health Act state and state that "Every healthcare provider must inform the user of the range of options generally available to the user; the benefits, risks, costs and consequences associated with each option.".[1,2] Informed consent should provide the patient with sufficient information, in a way that they can understand, to make an informed decision regarding their management and to comprehend the implications of acting on this information. The South African Society of Anaesthesiologists (SASA) recommends that the anaesthetist should advise the patient on the most appropriate treatment based on their personal experience and patient characteristics, including risks and benefits of the proposed technique as well as alternative options[2,3,4]. The patient should be directed to additional information where possible and thorough documentation of the consultation should be done.[2,5] The doctrine of informed consent was introduced into South African law in 1994 on appeal in the Cape Provincial Division, , in Castell v De Greef.[6,7] This case was important as it: imported and accepted the doctrine of informed consent into South African medical law; ousted medical paternalism in favour of patient autonomy; treated lack of informed consent as an issue of assault and not negligence; and established the yardstick of the "reasonable patient" as the test for informed consent and not that of the "reasonable doctor". The "reasonable patient" standard requires that the patient be told of all the material risks (risks with grave consequences regardless of the frequency it is statistically shown to occur)[8] that would influence a reasonable person in determining whether or not to consent to the treatment.[4] Further, available guidelines advise medical practitioners to give too much rather than too little information[4] and that an uninformed patient cannot provide informed consent.[5]

The performance of regional anaesthesia is a rapidly expanding field with benefits beyond acute pain relief[9], and its use warrants informed consent to allow shared decision making between the patient and anaesthetist. Studies have shown that South African anaesthetists do not regularly obtain, much less document, adequate informed consent for anaesthesia,[10,11] which is in conflict with the South African medical law.[12] Additionally, in an increasingly litigious society, documentation of consent may assist in defending against any litigation or professional complaint which may arise between the parties involved. Informed consent is a complex process involving

systemic, anaesthetic and patient factors which contribute to the failure of obtaining the legal standard of informed consent.[13]

In the United Kingdom, an analysis of the statistics of legal claims relating to anaesthesia in the National Health Service (NHS) were reviewed for the period of 2008-2018.[14] Out of 1230 legal claims identified, 297 (24%) pertained to regional anaesthesia, with 82 (4%) of claims directly related to consent. A South African study showed that 78% (of a total of 129 anaesthetists) found the current method of obtaining verbal consent for procedures unsatisfactory[10] and that anaesthetists have suboptimal knowledge of South African Law pertaining to informed consent.[15] Furthermore, 93.8% of anaesthetists knew the potential legal implications of not obtaining and documenting informed consent but 61.8% admitted to not documenting consent regardless. A descriptive, observational study done in KwaZulu-Natal in 2016[16] investigated the informed consent process from patients' perspectives of 143 elective surgical patients and reported that only 57% of patients were given adequate information about their anaesthetic pre-operatively. In total, 83% of patients who signed the surgical consent form with the surgeon thought they had signed an anaesthetic consent form with the anaesthetist.

The South African healthcare system is overburdened and understaffed with excessive waiting times for elective surgeries, worsened by power cuts and the recent pandemic.[17] Thus, anaesthesia providers face many limitations when obtaining informed consent such as limited time to assess each patient, language barriers and pressure to not unduly delay an already saturated surgical list.[16] By using a standardised anaesthetic consent form for the performance of regional nerve blocks, patients' autonomy and basic human rights are secured, despite a busy clinical setting, as is the completion and recording of medicolegal documentation for the practitioner.[18] We performed a quality improvement project to quantify the incidence of documented informed consent for the performance of PNBs before and after introduction of a standardised consent form. Factors that could influence the quality of patient recall of informed consent were also assessed.

Methods

A prospective quality improvement project was established after approval was obtained from the Human Resources Ethics Committee (HREC) of the faculty of Health Sciences of the University of Cape Town (UCT) (HREC ref:810/2021). Perioperative data was collected by members of the UCT anaesthetic department at Groote Schuur Hospital in Cape Town, South Africa. All PNBs performed by anaesthetists on elective orthopaedic surgical lists during two separate two-week periods before and after the introduction of a standard informed consent form (appendix 1), were included.

The first period of data collection was performed in order to quantify the documentation of informed consent as well as patient recollection of the informed consent discussion before the implementation of a standardized informed consent form. Every patient with adequate decisional capacity (defined as the ability to understand the information, appreciate the risks and benefits, and reason with the information) over 18 years of age that received a PNB performed by an anaesthetist was eligible to participate. Decisional capacity was assessed by both the surgeon when consent for surgery was taken prior to surgery and the anaesthetist interviewing the patient when informed consent was taken to participate in the study the day after surgery. Patients were interviewed the day after their procedure to assess recollection of the anaesthetic consent discussion. Patients were asked if they recalled the block discussion, whether any benefits were discussed, whether any risks were discussed and whether or not alternative options were discussed. In the 6-week period between the pre- and post-intervention audit, a standardised informed consent form was introduced to the department of anaesthesia. Forms were printed on brightly coloured paper and placed in visible places in the anaesthetic department and theatre induction rooms. The quality improvement project was presented at a departmental academic meeting and weekly reminders to use the form were posted on the various department WhatsApp® groups. The standardised form documented risks, benefits, alternatives discussed and whether consent was granted by the patient. The patient was not required to sign the consent form as this is not legally required to validate consent, nor is it recommended by SASA. Two QR codes were available on the form. One linked to the information leaflets for the patient, taken from the South African Society for Regional Anaesthesia (SASRA) guidelines, with all the risks, benefits and alternatives

for each PNB (appendix 2). The second QR code linked to relevant information to be discussed with the patient for the doctor's perusal (appendix 3). The anaesthesia providers weren't informed of the pre-intervention audit results or of the start of second audit. As the post-intervention audit commenced, the weekly reminders stopped.

During each two-week audit, the anaesthetic charts for elective cases were reviewed to find all eligible patients who received PNBs. An investigator recorded whether or not informed consent for the PNB was documented after recruiting the patient. An investigator interviewed the patient the day after their surgery to assess their recollection of the PNB consent. Observational data was collected anonymously by the study coordinators.

Based on the observation of current practice, the proportion of documented informed consent was estimated to be around 20%. Given an expected improvement to at least 50% after introduction of a standard informed consent form, a sample size of 39 patients was required in each group to detect a difference in proportions with a power of 80% and a two-sided alpha of 0.05. Data were entered into a Microsoft Excel spreadsheet. Descriptive statistics, including means, modes and percentages, were reported as appropriate to assess the data. A McNemar paired sample test for differences in proportions was used to compare documented consent incidence in the pre- and post-intervention data collection periods. Regression analysis was used to explore the effect of prespecified confounders (documented consent taken; benefits discussed; alternatives discussed; complications discussed and whether autonomy was documented) on the association between the recall of block consent, alternatives, benefits and complications discussed in the pre- and post-intervention rounds.

Results

We recruited a total of 43 patients (2 were excluded as they were younger than 18 years old, 2 were excluded due to lack of decisional capacity) in the pre-intervention round and 45 patients (2 were excluded due to being younger than 18 years old) in the post-intervention round.

Informed consent was documented in 7.7% of cases in the pre-intervention audit. Whether risks, benefits or alternatives had been discussed was not specified. In the post-intervention audit, documentation of informed consent for PNBs had improved to 60.5%. Documentation of benefits (51.2%), alternatives (48.8%), complications (51.2%) and autonomy (51.2%) discussed also improved (figure 1). Anaesthetists in our setting were 4.16 (95% CI -6.67 to -2.98, p<0.001) times more likely to take documented informed consent when provided with a standardised form.

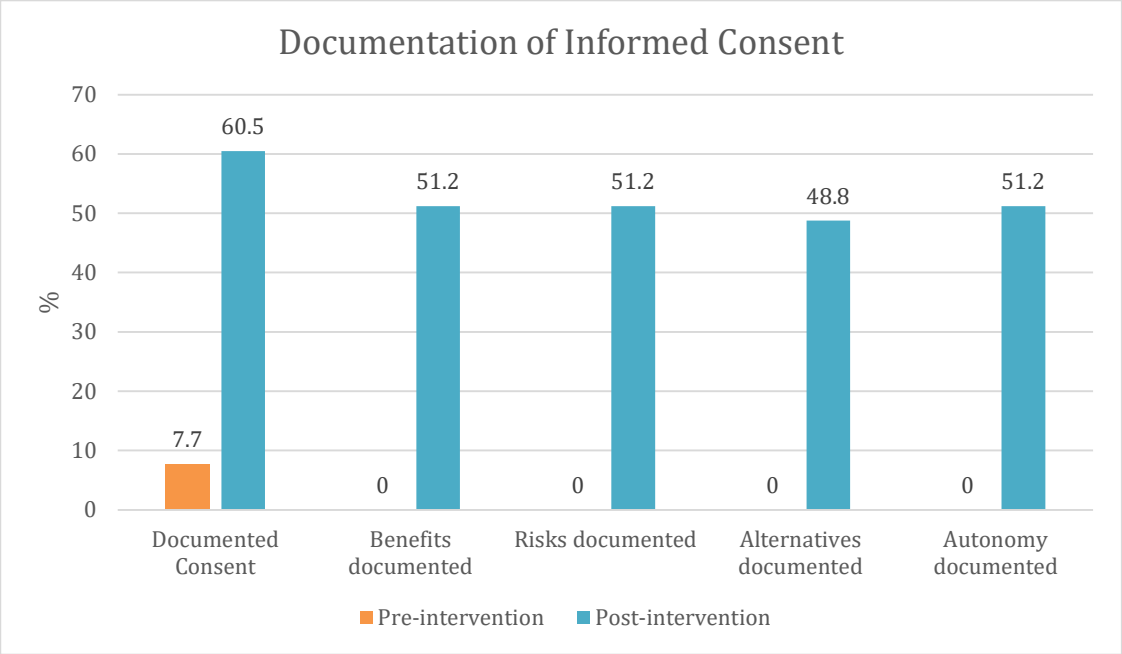

Figure 1: Graph comparing incidence of documented informed consent in the two data sets

In the pre-intervention round, most patients could recall the block being discussed (84.6%) even though consent was only documented in 7.7% of cases. Discussion of benefits, alternatives or complications were not documented in the pre-intervention audit, but 48.7% could recall alternative options, 56.4% could recall one or more benefits and 10.3% could recall one or more complications discussed (figure 2). During the post-intervention round, 90.7% of patients could recall the block being discussed, 74.4% could recall alternative options, 23.3% could recall benefits and 53.5% could recall complications being discussed (figure 2).

The regression analysis showed that prespecified confounders (documented consent taken; benefits discussed; alternatives discussed; complications discussed and whether autonomy was

documented) influenced the patient recall of the block - in the first round patients were 18.57 times less likely to recall the block compared to 2.25 times less likely to recall the block in the second round as well as benefits and complications discussed. Overall, recall of the block consent was most influenced when benefits were discussed with the patients (95% CI -20.026 to -14.643, $p<0.001$).

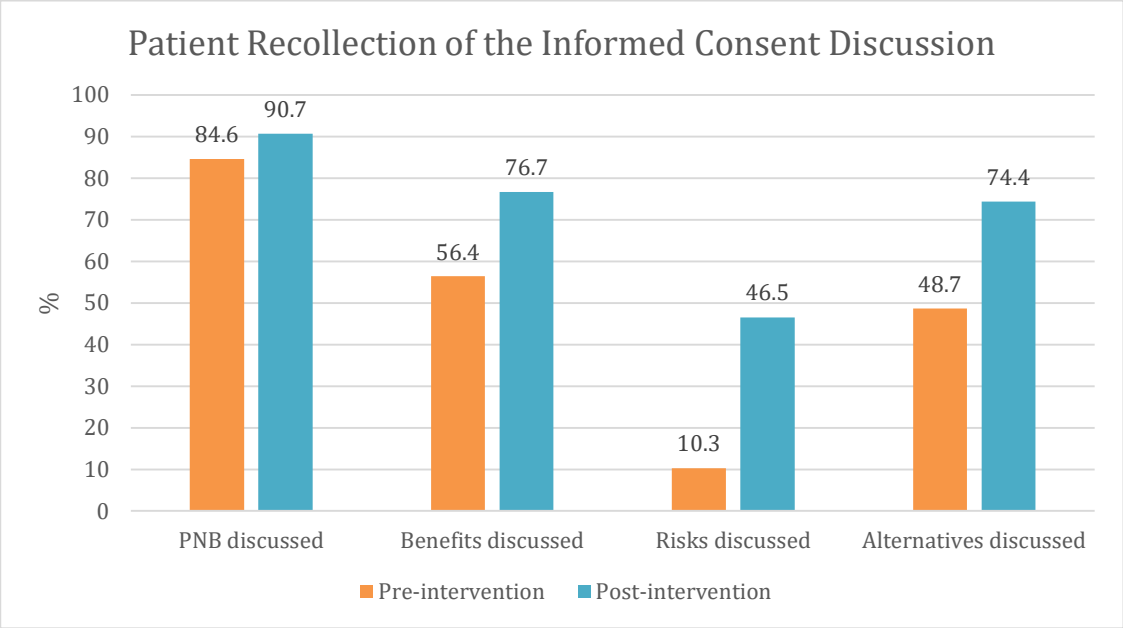

Figure 2: Graph comparing patient recollection

Discussion

Documentation of informed consent for PNBs as a baseline was poor. After a standardised consent form was introduced the documentation of consent improved significantly ($p<0.001$). The recollection of the consent process by patients also improved, specifically the alternatives, benefits and risks discussed.

This is the first quality improvement project of its kind in South Africa. A similar observational study (unpublished thesis, accepted MMed) was conducted in South Africa at Wits University in 2016.[11] The study investigated documented informed consent and patient recall for PNBs of patients undergoing upper limb surgery at Chris Hani Baragwanath Hospital. This study reported that documentation of informed consent in the patient's notes was present in only 3% of patients but still did not meet the HPCSA's guidelines for informed consent. Patient recollection of the consent process was also assessed and only 20% of patients had adequate knowledge about the PNB they had received. Observational studies have been conducted in South Africa that interrogate the incidence of documented informed consent in anaesthetics[10,11] and describe the perspectives of anaesthetists regarding the need for standardised informed consent forms.[5,10,11,18,19] The results of our study indicates that availability of such a form can improve documentation and enhances patient recollection of informed anaesthetic consent.

There is limited international literature about quality improvement in documented consent. One similar study was conducted in the Caribbean by introducing a general consent form stating the type of anaesthetic(s) discussed which the patient was asked to sign.[20] Specific/detailed risks and benefits were not indicated on the form. The separate written consent had a positive impact on the patients' understanding of the nature and purpose of the intended anesthesia procedures ($P = 0.04$), satisfaction with the adequacy of information provided about common side effects ($P < 0.001$) and rare but serious complications ($P = 0.008$). Incidence of documented informed consent was not assessed.

A noteworthy occurrence happened during the data collection whereby a patient received bilateral interscalene blocks after the non-operative side was initially blocked followed by an interscalene

block being performed on the operative side. The patient subsequently developed respiratory distress requiring intubation and ventilation in ICU for 12 hours. Although the clinician concerned confirmed that verbal consent was obtained, there was no documentation of informed consent – including risks such as the one that occurred. This highlights the dire need for the incorporation of such a form into the anaesthetic chart to encourage routine use.

While written consent is not a legal requirement, it is a strong defence against any professional or litigious complaints lodged against a practitioner. Without written consent, complaints that otherwise could have been dismissed immediately (either by a patient's attorney or by a court) may go on for years before appearing in court, becoming a financial and emotional expense that could have been avoided.

During the post intervention data collection, a significant improvement of documentation of informed consent was noted. There were also incidences during the post intervention data collection where the form was not used but doctors took the time to document their informed consent in the margins of their charts, an indicator that having the forms available and having discussions around the topic improves awareness of the importance of documenting informed consent to the extent that doctors took it upon themselves to make sure it was done. Patient recollection of alternatives, risks and benefits discussed also improved after the intervention, suggesting that the standardised consent form encouraged anaesthesia providers to improve the way in which they obtained informed consent. A standardised consent form assists in broadening the discussion regarding informed consent.[19] The QR-code linked information also lent strength to the consent process and empowered the anaesthesia provider. While national guidelines and standardised forms would be invaluable in aiding documented consent, we suggest that adding an informed consent section with such QR-code linked patient and provider leaflets to the standard institutional anaesthetic forms could add immense value to the consent process.

Limitations

The standard for risks and benefits discussed and recalled by the patients in this study was not specified according to individual blocks or material risks. Forms were printed and distributed by

the investigators which limits the sustainability of this intervention. The post intervention data collection was performed six weeks after the introduction of the form. Normalising a change in practice in a complex system like healthcare is not easy. Another round of data collection six months to a year post intervention, without knowledge that of the study being conducted, to assess longevity of this intervention would be revealing. A larger sample size and a longer collection period would also be beneficial to more accurate data. While documenting consent may provide a defense for the anaesthesia provider in cases of negligence, the nature and quality of the informed consent discussion between the patient and doctor is the major factor of true informed consent.[19]

Conclusions

A dedicated regional anaesthesia consent form significantly improved the documentation of informed consent, assisting in protecting the anaesthetist from any possible litigation. The quality of informed consent being obtained before performing a PNB also improved, this should protect patient autonomy and encourage them to actively participate in the decision making of their anaesthetic.

A separate consent form is cumbersome and easily overlooked in a busy setting. Integrating informed consent documentation into the standardised anaesthetic chart may assist practitioners to improve the quality and documentation of informed consent.

This study was aimed at consent pertaining to PNBs but we would recommend including a section that covers consent for all types of anaesthesia (PNBs, neuraxial, sedation and general anaesthetics). In our institution we are currently working on implementing such a section on our anaesthetic charts that are used for all procedures.

Other information

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Appendices

1. UCT Anaesthetics PNB Informed Consent form
2. Relevant information re. PNBs for the anaesthetist

ANAESTHETIC CONSENT FORM

HOSPITAL STICKER

DEPARTMENT OF ANAESTHESIA & PERIOPERATIVE MEDICINE
UNIVERSITY OF CAPE TOWN

Planned procedure:

Planned Regional Anaesthesia technique:

Benefits	:	1.	☐
		2.	☐
		3.	☐

Common complications:		1.	☐
		2.	☐
		3.	☐

Rare complications:		1.	☐
		2.	☐
		3.	☐

Very rare complications:		1.	☐
		2.	☐
		3.	☐

Alternatives:	☐

Patient informed of right to refuse:	Y / N

Patient gives consent for above mentioned block:	Y / N

Dr: _____ Date: _____

DEPARTMENT OF ANAESTHESIA
& PERIOPERATIVE MEDICINE
UNIVERSITY OF CAPE TOWN

Peripheral Nerve Block informed consent information

General Complications

Common:
Motor Block
Failed block

Rare
Haematoma – small chance
Local discomfort (Due to going through soft tissue, usually short duration)

Very Rare
IV administration - LA toxicity (convulsions, dysrhythmias)
Sepsis – surface infection or abscess
Nerve damage – temporary or permanent

Block specific complications

Supraclavicular
Pneumothorax

Interscalene
Horner's syndrome
Ipsilateral diaphragmatic paralysis

Alternatives
Other regional techniques
IV analgesia administration
Inform patient of right to refuse block and that refusal will have no impact on surgery