

## Original Study

# A PROSPECTIVE STUDY OF ACUTE SPINAL BLOCKADE COMPLICATIONS OCCURRING IN 24 HOURS AT LABASA DIVISIONAL HOSPITAL – FROM NOVEMBER 2019 TO NOVEMBER 2020

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## ABSTRACT

**Objective:** To determine the incidence of acute spinal blockade complications and the association of frequent spinal blockade complications and acute spinal blockade complications.

**Methodology:** A prospective, qualitative survey of 685 adults at Labasa Hospital was done from November 2019 to November 2020 to determine the incidence of having spinal blockade complications in 24 hours. Cross tabulation was used to determine the strength of association between frequent spinal blockade complications and the incidence of acute post spinal blockade complications.

**Results:** The incidence of acute post spinal complications was 18%. 685 participants were entered into analysis. 17% of patients thereby had frequent spinal during the study period. The Odds Ratio of frequent spinal blockade complications to acute post spinal complications was found to be 2.56 (Confidence Interval: 1.62-4.02).

**Conclusion:** The study describes the cohort getting spinal blockades in Labasa Hospital. In addition, this audit highlights the incidence of acute post spinal blockade complications. The strong association of acute post spinal blockade complications and frequent spinal blockades is confirmed. The author believes that this lays groundwork for studies showing the validity of doing post anaesthesia visits and increasing research into the dangers of having frequent spinal blockades.

## INTRODUCTION

In Fiji, anaesthesia providers don't routinely do post anaesthetic visits, therefore, complications can theoretically, be missed. Spinal blockades constitute a major proportion of anaesthetic procedures in Labasa Hospital. (35) Anecdotally, some patients receive frequent multiple spinal blocks over their hospital stay. In addition, there is a paucity of evidence linking frequency of spinal anaesthesia and complications. (27) Literature has shown the proven safety record of spinal blockades. (2, 7, 29, 31, 32) Despite this, there is evidence of complications occurring secondary to spinal anaesthesia (9, 12, 14, 16, 18, 20, 24, 25, 33). Though the complication rates are low, some complications are serious. (12, 18, 20, 23)

The incidence of complications of patients undergoing spinal blockades at Labasa Hospital is unknown. The information on the patients receiving spinal blockades at Labasa Hospital is non-existent as well. In addition, it is

also unknown if the select few that receive frequent spinal blockades develop complications in comparison to those having only one spinal blockade at that current admission.

This study will determine the incidence of acute post spinal blockade complications at Labasa Hospital. The descriptions of those developing acute complications to spinal blockades will also be stated. In addition the incidence of frequent spinal blockade complications will be determined too. Likewise, the study will also look at the strength of association between frequent spinal blockades and the incidence of acute post spinal blockade complications.

## AIMS

1. Determine the incidence rate of acute post spinal blockade complications at Labasa Divisional Hospital for November 2019 to November 2020.

2. Determine the incidence of frequent spinal blockades at Labasa Divisional Hospital for November 2019 to November 2020.
3. Calculate any association between frequent spinal blockades and acute post spinal blockade complications.

## OBJECTIVES

1. Describe patients undergoing a spinal blockade in Labasa Hospital over the November 2019 to November 2020 time period.
2. Express incidence of frequent spinal blockades and calculate the association of frequent spinal blockades to acute post spinal complications at Labasa Hospital for the same period.
3. Determine the acute complication incidence occurring post spinal blockade at Labasa Hospital from November 2019 to November 2020.

## VARIABLES AND DATA COLLECTION TECHNIQUE

This was a prospective, observational descriptive study. It is descriptive in that it determines the incidence rate of post-spinal blockade complications at Labasa Hospital from November 2019 to November 2020. Patients that received a spinal blockade at Labasa Hospital were followed up day one post-spinal blockade for any major complications that they may have developed. Informed consent was taken from the patient or relative during the preoperative assessment by the Labasa Divisional Hospital Anaesthesia team. The procedure particulars were noted in the data collection sheet by the anaesthetist performing the anaesthetic procedure. At 24 hours post spinal blockade the author went to assess the patient to conduct the interview as per the question sheet on the data collection sheet. Any further information needed to be filled was obtained from the patient folder.

All the complications will be managed as per standard management guidelines as per the instruction of the Anaesthetic Consultant. The complications and their management will be discussed as follows.

- For any cardiopulmonary arrest, the ACLS guidelines will be followed with correction of likely causes of arrest. If necessary to convert to general anaesthesia this will be done with clinical assessment of post-operative ventilation in ICU.
- For the occurrence of vertebral canal hematomas, prompt diagnosis within 12 hours and a high clinical suspicion in those on anti-coagulopathic drugs, deranged coagulation states or thrombocytopenia may warrant a prompt evacuation of a spinal hematoma.

- For infections such as spinal abscess or infective meningitis the patients will be treated as per standard protocol with antibiotics and spinal abscess incision and drainage.
- For neurological deficits they will be investigated so that other causes can be ruled out. There is no definitive treatment guideline for managing permanent neurological deficit post-spinal in Fiji.
- The management algorithm for Post Dural Puncture Headaches is dependent on severity. This will include bed rest and lying in the prone position. Oral or intravenous fluids to maintain hydration with oral analgesics such as paracetamol, aspirin or codeine. Caffeine ingestion through tea, coffee or Coca Cola drinks will be encouraged. Prolonged or severe headaches can be treated with a blood patch. This is the injection of 20ml of the patient's blood into the epidural space to seal the hole and stop CSF leakage.

The demographic information entered into data collection sheet from patient folder review and post spinal blockade rounds will be age, ethnicity, procedure, parturient or not, surgical specialty, surgical pathology, emergency/elective and ASA status.

The patients will be described by the following variables:

- Type of antiseptic prep which can include SVM, Betadine, Normal Saline and is acquired from the anaesthetic chart.
- Spinal needle gauge which can include any size gauge from 27-gauge to 18-gauge which is acquired from the anaesthetic chart.
- Spinal needle type which can be acquired from the anaesthetic chart.
- Spinal anaesthetic type, dose, and volume which can be acquired from the anaesthetic chart.
- Fentanyl dose which can be acquired from the anaesthetic chart
- Number of attempts which will be acquired from the anaesthetic chart.
- The presence of paraesthesia during insertion of spinal needle as reported by patient during post spinal rounds or as recorded by anaesthetist on Anaesthetic Chart.
- The total number of previous spinal anaesthetics received by patient within 30 day period obtained by history taking and by patient folder.

The following are the complications the author is hoping to capture during post spinal rounds the next day.

- The number of perioperative mortality within 24 hours. This can be obtained from patient folders and Ward Admission Registers.

- The number cardiopulmonary arrest and resuscitation within 24 hours of spinal block. This can be derived from patient folders.
- The number of unplanned post-operative Intensive Care Unit admissions within 24 hours of a spinal block. This can be derived from patient folders and ICU Admission Register.
- Presence of any sensory deficit more than 12 hours after spinal block. This can be obtained from patient history taking and physical examination during the spinal block post-operative rounds.
- Presence of any motor deficit more than 12 hours after spinal block. This will be derived from history taking and physical examination of patients during postoperative spinal block rounds.
- Presence of urinary or faecal incontinence more than 12 hours after spinal block. This will be derived from history taking and physical examination of patients during post-operative spinal block rounds.
- Presence of backache after spinal block. This will be derived from history taking and physical examination of patients during post-operative spinal block rounds.
- Presence of headache after spinal block. This will be derived from history taking and physical examination of patients during post-operative spinal block rounds.
- Number of failed or inadequate spinal blocks necessitating conversion to sedation or general anaesthesia to allow procedure commencement.
- Any other complaints or problems voiced by the patient or pertinent physical findings found during post spinal rounds that will be entered into the Study Data Sheet.

The following pre-spinal blockade conditions are too be described also by the author: preoperative Systemic Inflammatory Response Syndrome / Sepsis / Septic shock, ischaemic heart disease, diabetes mellitus 1 or 2, hypertension, Valvular heart disease, congestive cardiac failure, any shock requiring inotropic support, pre-existing neurological deficits, pre-existing neuromuscular disorders, Pre-eclampsia toxemia / eclampsia. The data will be entered into data collection forms as the author conducts post spinal rounds. This will be from patient history taking, physical examination and investigations as recorded in the patient folders and anaesthetic progress as recorded in the Anaesthetic Chart.

## SAMPLING

The cohort was patients 18 years and over that was receiving spinal blockade at Labasa Divisional Hospital. Eligibility criteria were for informed consent to be taken and patient over 18 years old and all combined spinal epidural blockades were excluded. The data collection and recruitment was conducted from November 2019 to

November 2020. Follow up was only done to 24 hours post spinal blockade.

## DATA PROCESSING AND ANALYSIS

Data was collected via a data collection form. The data was input into Microsoft Excel and SPSS spreadsheets. The individual forms were assigned Identification numbers to ensure confidentiality of patients. Data was classified into Nominal, Ordinal and Scale data types. Means and standard deviations were derived on Scale data types. Frequencies were also calculated to determine counts and percentages and rates. Measures of association of the Nominal data types were done with SPSS Cross tabulation. Pearson Chi-Square Method to determine association presence. Cramer's V method for Symmetric Measure of association strength. Odds and Risk ratios was then calculated from the cross tabulation to show strength of association. Moreover, confidence intervals were also calculated to show presence or absence of statistical significance.

## ETHICS

Ethical approval was granted by the Labasa Divisional Hospital Ethics Committee and the FNHERC. The study will benefit clinicians and patients. To begin with the benefits for the clinician are determination of spinal blockade complication rate for Labasa Hospital. This can lead one to hypothesize on possible causes. This study will benefit the patient in that there will be an active search for post spinal complication. At present there are no post anaesthesia ward rounds. Patient care post anaesthesia is reliant on the primary team and nursing staff. Expertise however in recognizing early post-spinal blockade complications lie with department of anaesthesia. This action thereby promotes good practice of post-operative or post anaesthesia visit.

## RESULTS

Over one thousand seven hundred spinal blockades were conducted at Labasa Divisional Hospital from November 2019 to November 2020. Figure 1 highlights the recruitment process of participants. In summary, 39.9% (685 out of 1715) of the population was included into the study. 792 participants were not recruited into the study. Reason being anaesthetist may have forgotten or was too busy to recruit into study. However out of this 792, 269 were not followed up because it coincided with the first wave of COVID that occurred in Labasa Divisional Hospital. The author was involved in the active management of Covid positive cases so was unable to

follow up the patients in the ward as he was isolated as per Containment Phase protocols. 78 refused to partake in the study and 160 patients did not have post spinal rounds done. Therefore only 685 were entered into the SPSS database.

Figure 1: Flow diagram of participant selection for Acute Complication of Spinal Blockade study

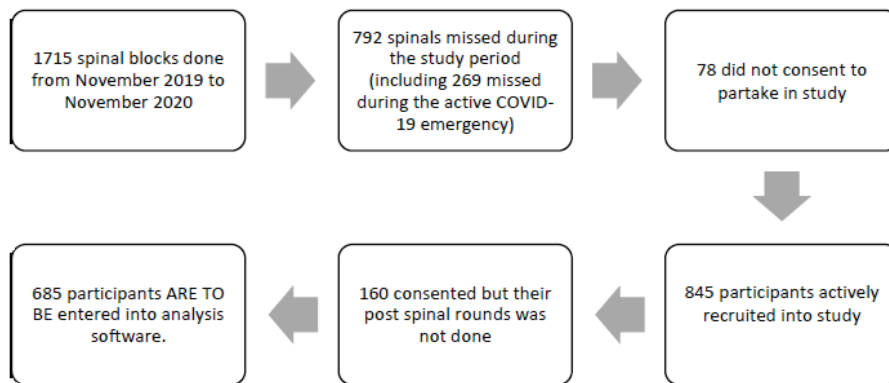


Table 1 Patient Demographics of cohort of patients undergoing spinal blockade at Labasa Divisional Hospital from November 2019 to November 2020. SD is Standard Deviation. N is count of patients. ASA is American Society of Anaesthesiologists. n = 685 patients. N is patient count. \* is indicating patient demographic count that is important.

Age, Mean (SD),	38.7, (16.7)
Race	<b>N (%)</b>
I Taukei,	432 (63.07)*
Fijian of Indian Descent	212 (30.95)
Fijian of Other Descent	41 (5.99)
American Society of Anaesthesiology Classification	
ASA 1	102 (14.89)
ASA 2	378 (55.18)*
ASA 3	89 (12.99)
ASA 4	113 (16.50)
ASA 5	3 (0.44)
Is the patient pregnant or not?	
Yes	314 (45.84)
No	371 (54.16)
Urgency of the surgical procedure	
Elective	215 (31.39)
Emergency	470 (68.61)*
Medical Speciality that conducted the surgical procedure	
General Surgery	96 (14.01)
Orthopaedic Surgery	212 (30.95)
Obstetrics and Gynaecology	361 (52.70)*
Surgery	
Urology	16 (2.34)
Known Pre-spinal blockade Comorbid conditions	
Sepsis, N (%)	157 (22.9)*
Type 2 Diabetes Mellitus	190 (27.74)*
Hypertension	136 (19.85)
Ischaemic Heart Disease	52 (7.59)
Valvular Heart Disease	17 (2.48)
Congestive Heart Failure	11 (1.61)
Pre-existing Neurological deficit	8 (1.17)

Patient characteristics are shown in Table 1. Many of the spinal blockade patients were between 20 to 40 years of age. Over 60% of participants were I-Taukei. 55% of participants had an ASA 2 classification. 45% of the participants were pregnant with 68% of all procedures being emergency cases. The Surgical and Obstetrics departments were about half of both specialities that received spinals. Less than a third of patients were diabetic with more than a fifth having a concurrent septic condition. Most cases done in this study period were emergencies.

The mean volume of local anaesthetic used was 2.4 mLs of Heavy Bupivacaine. Most patients needed 1 to 2 spinal needle insertion attempts to complete a spinal blockade. There was a patient though who had about 22 spinal needle insertion attempts before successful Cerebrospinal fluid flow was achieved. Most of the patients used the spinal needle gauges of 25

(62%) and 27 (38%). Nearly all of the anaesthetists at Labasa Divisional Hospital used SVM alcohol to do skin prep for the spinal blockade procedure. Frequent spinal blockade was defined by the author as having two or more spinal blockades within thirty days of the previous spinal blockade. 17% of patients thereby had frequent spinals during the study period.

Table 2 Variables of the spinal blockade particulars of patients having spinal blockades at Labasa Divisional Hospital from November 2019 to November 2020. SD is standard deviation. n=685. N is patient count.

Volume of Spinal Local anaesthetic used in mLs, Mean, (SD)	2.41, (0.44)
Number of attempts before a successful block achieved, Mean, (SD)	1.89, (1.90)
Paraesthesia during administration of block	<b>N (%)</b>
Present	24 (3.50)
Absent	661 (96.5)
Antiseptic preparation used	
SVM Alcohol	669 (97.7)
Chlorhexidine	12 (1.80)
Betadine®	4 (0.60)
Spinal Needle Gauge	
20 Gauge	2 (0.30)
25 Gauge	425 (62)
27 Gauge	258 (37.70)
Fentanyl Dose (mL), Mean, (SD)	0.20 (0.18)
Intrathecal Morphine (mL), Mean, (SD)	0.01 (0.03)
Frequent spinal blockade	<b>N (%)</b>
Present	117 (17.10)*
Absent	568 (82.90)

The following outcomes were assessed at the 24 hour follow up. Table 3 has it listed. 6 participants died within 24 hours of a spinal blockade. Moreover, 14% of participants complained of backache, while 7% said they had headaches.

Table 3 Comparison of complication rates of Labasa Divisional Hospital versus Published Literature. NA is not applicable and refers to data unknown. N is count of complications detected while n refers to total number of patients in study.

Complications	Labasa; 2022 n = 685	Vandam; 1954, 1960 n = 10098	Horlocker ; 1997 n = 4767	Auroy; 2002 n = 35439	Cook; 2009 n = 324950
24-hour all-cause mortality, N (%)	6 (0.9)	NA	NA	4 (0.0001)	NA
Unplanned Intensive Care Unit admission, N (%)	1 (0.1)	NA	NA	26 (0.0007)	3 (0.000009)
Presence of sensory deficit below level of spinal blockade >12 hours, N (%)	4 (0.6)	66 (0.00001)	6 (0.001)	12 (0.0003)	13 (0.000004)
Presence of Lower Limb Motor deficit >12 hours, N (%)	6 (0.9)	2 (0.00001)	4 (0.001)	11 (0.0003)	13 (0.000004)
Headache, N (%)	50 (7.3)	1414 (14)	62 (1.3)	NA	NA
Backache, N (%)	96 (14)*	NA	NA	NA	NA
Conversion to sedation or general anaesthesia, N (%)	12 (1.8)	NA	NA	NA	NA
Urinary incontinence >12 hours, N (%)	10 (1.5)	NA	NA	NA	NA
Complication Count, N (%)	124 (18.1)*	1484 (14.7)	95 (2)	79 (0.002)	82 (0.00004)

Table 4 Associations of frequent spinal blockades and the occurrence of acute spinal blockade complications. \* indicates statistical significance. N is patient count.

Pearson Chi-Square Test, Value (Asymptotic Significance at dF=1)	17.4 (0.000)*
Cramer's V, Value (Approximate significance for Symmetric Measures)	0.159 (0.000)*
Odds Ratio, Value (95% Confidence Interval)	2.56 (1.63-4.02)*
Relative Risk, Value (95% Confidence Interval)	2.07 (1.49-2.87)*

The results of the analysis of the associations between frequent spinal blockades and occurrence of acute spinal blockade complications are listed in Table 4. Pearson Chi-Square Test shows that there exists a relationship between frequent spinal occurrence and the incidence of acute spinal blockade complications. Cramer's V shows that the strength though may be mild (as 0.159 is close to 0). The odds ratio and risk ratio is about 2.5 and 2 respectively. With their confidence interval not passing 0 it is likely statistically significant. Table 5 shows that the incidence of acute spinal blockade complications are associated with Sepsis, Hypertension and diabetes and weakly associated with pregnancy.

## DISCUSSION

The participants of the study were found to be mainly young I-taukei ethnicity undergoing emergency procedures. Moreover, about a fifth was found to have diabetes, sepsis or hypertension. The study was able to infer the incidence of acute post spinal complications at 18%. The frequent spinal blockade rate was found to be 17%. Frequent spinal blockades too were found to be

weakly associated with acute spinal blockade complications. A person having a frequent spinal was 2.6 times more likely to develop an acute spinal complication. Because the confidence interval does not pass 0, it is statistically significant. Vandam, Horlocker, Cook & Auroy showed complication rates in their respective

studies of 14.7%, 2%, 0.002%, and 0.00004% respectively (1, 4, 14).

When compared to Labasa study of 18%, it seems to be closer to Vandam's study. The limitations of the study discussed later may be a reason for the differences. (1, 4, 14, 29, 30) Moreover, the author would like to postulate that the criteria for classifying complications in this study were not as stringent as other studies. Auroy's study and Cook's study looked only for clinically significant permanent harm. With these criteria, for instance, Cook screened about 70 of the cases that were reported to the NAP3 team. (4) With that they picked out only 54 cases that were the bases for their analyses in reaching their complication rates. With this they also only did a 2 week Census of CNB procedures and then they estimated the total number of patients from this 2 week census. Therefore, one can see the differences in methodologies and analytical methods employed showing differences in this study and the others. The results are similar to Vandam's because Labasa study method was similar. The author counted all the participants in the study similar to how Vandam did. Goyal, Tarbiat and Wipli published case reports of patients that underwent frequent or repeated spinal blockades that developed complications (9, 27, 36). This study shows that although the association is weak because the Cramers V value is 0.16 the odds ratio of 2.6 is statistically significant. This showed that patients having frequent spinal blockades have a 2.6 times more likely to develop acute



complications as compared to those who don't have frequent spinal blockades.

This study had limitations. Firstly, the sample audited was only 40% of the total population that had spinal blockade complications from November 2019 to November 2020. Taking this into account, one can question whether this is a true representation of the study population. There needs to be a better designed study with more robust sampling to remedy the validity of this study. With a more representative sample or including the whole population, the complication rates would be closer to the true incidence of acute spinal blockade complications. Another limitation is the bias as the study was not blinded. The author was involved in majority of the capturing cases and was also the primary investigator when looking for the outcomes 24 hours later. In addition, there was also the limitation of time delay bias. Most of the complications occur more than 24 hours after a spinal, like post puncture dural headache, backache and neurological sequelae (3, 4). A suggestion would be to design a study whereby more thorough follow-up can be done over 1 day, 3 days, 1 week, and 1 month, 6 months and 1 year period. Thereby, this would ensure capturing the true incidence of post spinal blockade complications. (7)

To add on, this study had a subjective post spinal interview and user dependent objective assessment. Whether the complication symptoms elicited was due to a true post spinal complication or another pre-existing condition was beyond the scope of the study design. This may be another reason for the big difference existing in the complication rate of other studies in relation to this study. One opinion that the author has after conducting this research is the need for post anaesthetic visits of all patients that undergo anaesthesia. The above study highlighted the occurrence of spinal blockade complications that were before not well known. Despite the weaknesses of the study design and limitations of the methodology employed, it can be seen that there exists complications that we as anaesthesia providers may be unaware of as we do not routinely conduct post-anaesthetic visits.

## CONCLUSION

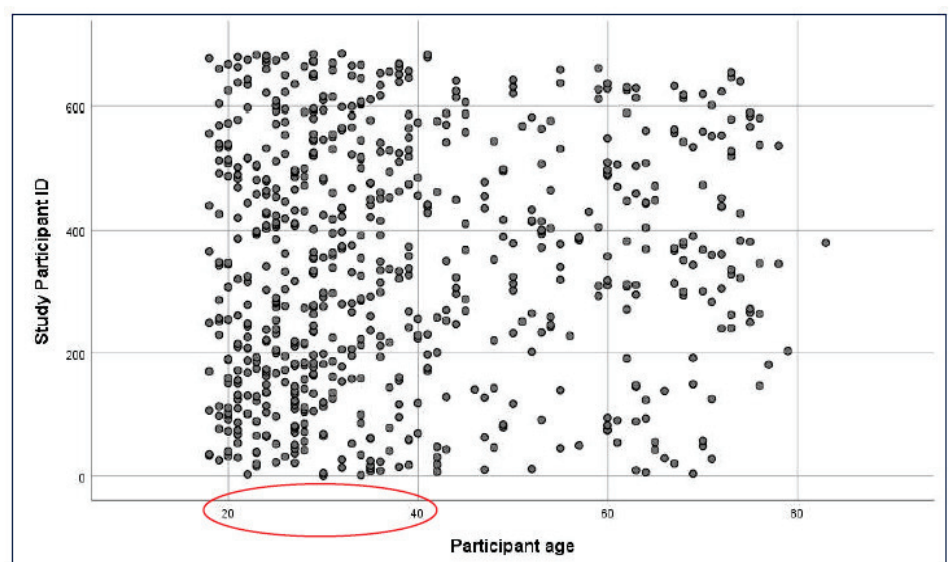
It is the author's recommendation that a stronger robust study design be drawn up so that more valid data is

drawn so better statistics and valid conclusions can be drawn to make practice changing recommendations for the benefit of the patients undergoing spinal complications.

## ACKNOWLEDGEMENT

- The Lord Almighty
- Dr Jocelyn Christopher
- Dr Emily Fuakilau
- Dr Maurice Kologa
- Dr Maika Seru
- Dr Ravnir Narayan
- Dr Epeli Serulevu Momo
- Dr Adilagi Vedewaqa
- Dr Katarina Moceleka
- Dr Allan Seniloli
- Dr Sweta Mudarlier
- Dr Watisoni Soloto
- My wife, Dr Timaleti Vateitei

Figure 2: Patient Age as reflected on a Simple Scatter Plot Chart.



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