

# A Prospective Study to Compare Routine versus Need Based Change of IV Cannula on Development of Infusion Phlebitis in Adult Surgical Patients

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**Abstract:** (IV) Intravenous therapy is one of the most commonly performed procedures in hospitalized patients yet phlebitis affects 27% to 70% of all patients receiving IV therapy. The incidence of phlebitis has proved to be a menace in effective care of surgical patients, delaying their recovery and increasing duration of hospital stay and cost. The recommendations for reducing its incidence and severity have been varied and of questionable efficacy. The current study was undertaken to evaluate whether elective change of IV cannula at fixed intervals can have any impact on incidence or severity of phlebitis in surgical patients. All patients admitted to the Department of Surgery, SMIMS undergoing IV cannula insertion, fulfilling the selection criteria and willing to participate in the study, were segregated into two random groups prospectively: Group A wherein cannula was changed electively after 24 hours into a fresh vein preferably on the other upper limb and Group B wherein IV cannula was changed only on development of phlebitis or leak i.e. need-based change. The material/brand and protocol for insertion of IV cannula were standardised for all patients, including skin preparation, insertion, fixation and removal. After cannulation, assessment was made after 6 hours, 12 hours and every 24 hours thereafter at all venepuncture sites. VIP and VAS scales were used to record phlebitis and pain respectively. Upon analysis, though there was a lower VIP score in group A compared to group B (0.89 vs. 1.32), this difference was not statistically significant ( $p$ -value = 0.277). Furthermore, the differences in pain, as assessed by VAS, at the site of puncture and along the vein were statistically insignificant ( $p$ -value > 0.05). Our results are in contradiction to few other studies which recommend a policy of routine change of cannula. Further we advocate a close and thorough monitoring of the venepuncture site and the length of vein immediately distal to the puncture site, as well as a meticulous standardized protocol for IV access.

**Key words:** IV cannula, thrombophlebitis, infusion phlebitis, cohort study.

## 1. Introduction

Infusion therapy has become an indispensable part of treatment in almost all surgical inpatient cases. Admission of the patient to the wards or ICU, preparing the patient for any surgical intervention as well as conservative management of a number of diseases requires the administration of intravenous medication. Cannulation, as a procedure, has evolved extensively since its origin as a crude and procedure in the 18th century yet complications continue to hinder their effective administration.

According to the available literature, the first study

observing the phenomena of “infusion phlebitis” was carried out in the early 19th century. It was not found to be very conclusive but it gave rise to the idea that the complications associated with infusion therapy are preventable. Much research was carried out to explore the various aspects of infusion therapy and the various risk factors leading to development of phlebitis. At first, the researchers were limited to catheter-indwell time till the researchers realized that other parameters like other patient and instrument factors may also contribute to the risk of development of phlebitis.

IV (intravenous) therapy is one of the most commonly performed procedures in hospitalized patients yet it is susceptible to innumerable infectious and non-infectious complications [1]. Centre for

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Disease Control and Prevention defines phlebitis as the development of “warmth, tenderness, erythema or palpable venous cord”. Phlebitis affects 27% to 70% of all patients receiving IV therapy [2]. Even with improved medical facilities at our beck and call, the incidence of phlebitis has proved to be a continuous menace in effective patient care, both pre- and post-operative set up. Infusion phlebitis leads to pyrexia of unknown origin, bacteraemia and even thrombo-embolic events which not only delay complete recovery of the patient but also increase the convalescence and, in severe cases, may even prolong hospital stay.

Mechanical phlebitis occurs where the movement of a foreign object (cannula) within a vein causes friction and subsequent venous inflammation [3]. It often occurs when the size of the cannula is too big for the selected vein [4]. It has also been suggested that placement of a cannula near a joint or venous valve will increase the risk of mechanical phlebitis due to irritation of the vessel wall by the tip of the cannula.

The north-east part of India has been one of the lesser probed regions of our country when it comes to medical research. Being home to a large indigenous population and differing from other parts of the country in its lifestyles, health status, health-seeking behaviour and health-affecting factors, it remains as of yet uncharted territory. With diverse ethnic variations, the Sikkimese population is a rich mixture of Nepalis, Lepchas, Bhutias and settlers from the plains.

Although a lot of studies have tried to the risk factors associated with infusion phlebitis, a precise and conclusive study on the subject eludes us. Through this study, we have tried to establish a relationship between the frequency of IV catheter change and the incidence of infusion phlebitis in Sikkimese patients among whom no such study has been attempted previously. The aim was to locally reinforce or refute the existing guidelines for peripheral IV catheter management.

## 2. Review of Literature

The history of intravenous therapy dates back to the middle ages. The first experiment with IV injections was carried out in 1640 by a gentleman’s hunting servant in Eastern German using quills and bladders of animals as instruments [5]. Similar experiments were done in 1656 by Christopher Wren, the astronomer, mathematician, and architect in Oxford, England and a group of scientists around the physicist Robert Boyle. As recorded by Dr. R. Lewis [6], during the cholera epidemic of 1831-1832, Dr. Thomas Latta pioneered the use of IV infusion saline. In the 20th century, World War II saw extensive use of IV devices and firmly established IV therapy as an integral part of medical practice [7].

Previously with limited knowledge about the dynamics of circulation, uncouth drugs and devices, limited to no means of maintaining an aseptic environment, a number of serious complications—some of which even led to death of the patient—were associated with IV transfusion. Certain problems associated with early IV drug delivery included migration of the steel needle, intra-arterial injection and breakage.

Even though IV therapy has become such a relevant and widely applied procedure in medical sciences, complications continue to limit its efficient use. In 80% of hospital admissions, an average of two vascular access devices per patient is required. Time and again researchers have sought ways to prevent or minimize their complications and a lot of commendable work has been done regarding the same, especially in the past decade. A study of the risk factors that lead to the development of infusion phlebitis has been attempted by many researchers with variable success.

There are more than 70 phlebitis assessment scales. In the studies that we reviewed, published tools such as the VIP (visual infusion phlebitis), INS (infusion nurses society), Maddox, Baxter, Lipman or Dinley scale were used but many authors did not state which

version they had used, despite wide variations between different versions. Other authors did not mention the source of their scale at all. In our study, we used the VIP scale which used pain, erythema, induration, palpable venous cord and pyrexia to grade the severity of phlebitis. VIP scale was used for its convenient application by the investigators as well as the staff and its easy interpretation. The presence and usage of such a large number of scales, however, makes it a mammoth task to standardize the findings of the various studies regarding phlebitis.

Another problem was the large discrepancy among the various studies regarding the definition of “phlebitis”. Most studies that we reviewed were not very specific about what they were looking for, that is, phlebitis. Few did mention their versions of phlebitis but were not in resonance with the Centers for Disease Control and Prevention’s definition of the same- “warmth, tenderness, erythema or palpable venous cord”. None of the various phlebitis assessment scales has been found to be better than any other [8].

Peripheral intravenous access is associated with a phlebitis rate of between 1.5% [9] and 60% [10]. Peripheral intravenous catheter-related bacteremia (CRBSI) rate of approximately 0.1% has been reported by Maki in 2006 [11]. One observational study followed 3,094 patients through their period of IV peripheral catheterization and found that the phlebitis rate of 2.3% and a bacteremia rate of 0.08% [12]. The second observational study compared intravenous catheters changer every 72 hours or 96 hours and found no considerable difference in the phlebitis rate [13]. One RCT that was cited was designed to compare two types of catheter material in addition to indwell times found that material of catheter is irrelevant [14].

The recommendation is not applicable to children or patients with poor veins. In recent years, studies suggest that the recommendation may need to be revised in lieu of the improved in catheter design and composition. On the other hand, based on level 1

evidence, the most recent Infusion Nursing Standards of Practice and the EPIC3 National Evidence Based Guidelines recommend that short peripheral catheters should be replaced when clinically indicated, unless the patient is receiving parenteral nutrition peripherally [15, 16]. The projected 5-year savings from implementing clinically indicated peripheral intravenous catheter removal policies is US\$300 million and 1 million health-worker hours in the United States alone [17, 18].

The currently accepted recommendation, that “there is no need to replace peripheral catheters more frequently than every 72 to 96 hours to reduce risk of infection and phlebitis in adults”, is interpreted in many hospitals to mean that IV cannulas need to be changed every 72 to 96 hours [19]. The credibility and necessity of this procedure has raised many questions in the recent past and a number of studies have been carried out to find out whether this convention ought to be followed or not.

A Cochrane study by Webster et al. [20] recently (2015) concluded that clinically-indicated change of cannula should be preferred over routine change of cannula since the former is more cost-effective and patient-friendly with no additive risk of infusion phlebitis. However a study by Washington et al. [21] that also took into consideration the IV medication being administered and the sex of the patient showed that females receiving higher doses of medications through IV line for longer duration and suboptimal nutrition were at a higher risk of developing phlebitis. This finding suggests that factors other than catheter indwelling time need to be considered and that patient factors might also have a significant role to determine the risk of development of infusion phlebitis in an individual.

Inter-rater reliability of phlebitis assessment is a problem whose range increases proportionately with the number of investigators. This was not a considerable source of error in our study as the number of investigators and outcome assessors was limited.

### **3. Objectives**

#### *3.1 Primary*

To compare if early elective change of IV cannula offers any advantage in prevention of infusion phlebitis in surgical patients.

#### *3.2 Secondary*

(1) To assess the incidence of infusion phlebitis in surgical patients.

(2) To establish correlation between incidence and severity of phlebitis according to the type of surgery/management and pre-existing co-morbidities.

(3) To establish a relation between BMI and the incidence of phlebitis.

### **4. Methodology**

#### *4.1 Outline of Study*

The adult patients admitted to the department of surgery undergoing peripheral IV cannula insertion were segregated into two groups based on the frequency and indication for their cannula change. The development of infusion phlebitis in these patients was noted and their prognosis observed.

#### *4.2 Approval*

Due approval of the Institutional Research Protocol Evaluation Committee and Institutional Ethics Committee was obtained prior to commencement of the study.

#### *4.3 Study Design*

The study was designed as a prospective comparative randomized study in 2 groups:

Group A: Patients undergoing elective IV cannula change.

Group B: Patients undergoing need-based IV cannula change.

The segregation of patients into the two groups was according to computer generated random list. Observer blinding was not feasible due to obvious

absence or presence IV puncture on contralateral limb which could not be hidden from the observer. Patient blinding was also not feasible due to similar reasons.

#### *4.4 Study Area*

The study was carried out in Department of Surgery, Central Referral Hospital, Gangtok.

#### *4.5 Study Population*

All adult patients admitted to the Department of Surgery during the period of the study, agree to participate in the study.

#### *4.6 Sample Size*

Since the range of reported incidence of infusion phlebitis in available literature ranges from 0-91%, it was not possible to reliably calculate the prospective sample size for a robust prospective study. Thus, all patients undergoing cannula insertion in Department of Surgery during the duration of the study were included.

#### *4.7 Randomization*

(1) Group A: Patients having their cannula changed electively, every 24 hours, placed on contralateral limb.

(2) Group B: Patients having their cannula changed as per need (on development of blockage, extravasation or phlebitis).

Randomization was according to computer-generated hospital number and was not based on any bias.

There was a wrist band in which time and date of insertion and group including time for inspection were recorded.

#### *4.8 Selection Criteria*

##### *4.8.1 Inclusion Criteria*

All adult patients admitted in the surgical ward who will receive parenteral medications, through IV cannula placed for more than 12 hours.

#### 4.8.2 Exclusion Criteria

- Patients who have had their IV cannula inserted outside the hospital.
- Patients who have a history of phlebitis in the past 1 year.
- Patients with multiple limb injuries.
- Patients with simultaneous multiple IV cannula insertions.
- Patients with known coagulopathies (both with hypo- and hyper-coagulation).
- Patients with central venous access or venesection.
- Patients not consenting to participate in the study.

#### 4.9 Method

Evaluating the amount of risk associated with various factors predisposing patient to phlebitis according to the Visual Infusion Phlebitis scale.

The make and material of cannula were same for all patients.

A standard protocol for insertion of IV cannula was employed for all patients, including skin cleaning and antisepsis, bevel down technique for venepuncture, and fixation using transparent adhesive. Cannula flushing with 5 mL of 50 U/mL heparin solutions was done every 12 hours for all patients.

After cannulation, assessments were to be made after 6 hours, 12 hours and every 24 hours thereafter.

#### 4.10 Data Collection

Personal details and illness of the patient of the patient were recorded following a written consent from the patient that he was willing to be a subject of the study. The consent form was written in Nepali for better understanding of the patient and in case of any doubt, and the entire information was verbally conveyed.

#### 4.11 Parameters Assessed

##### 4.11.1 Patient's Characteristics

- Age

- Sex
- Weight, height and BMI
- Diabetes mellitus
- Hypertension
- Known coagulopathy
- Other co-morbidities

##### 4.11.2 Disease Characteristics

- Type of management
  - Elective surgical
  - Emergency surgical
  - Non-operative
- Other diseases (non surgical)
- Diagnosis
- Surgery performed (if any)

##### 4.11.3 Cannula Characteristics

- Time of 1st IV cannula insertion
- Size of cannula

##### 4.11.4 Outcome Assessment

The assessor was either a doctor or a nursing staff having at least 5 years of experience.

The outcome assessments made were:

- Pain: using (VAS) Visual Analog Scale [7].
- Phlebitis: Using (V.I.P.) Visual Infusion Scale according to which a score will be provided to all patients at designated intervals.

**Table 1 Visual infusion phlebitis scale.**

0	IV site appears healthy	
1	One of the following signs is evident	Slight pain near IV site OR Slight redness near IV site
2	Two of the following are evident	Pain at IV site Redness Swelling
3	All of the following signs are evident	Pain along path of cannula Redness around site Swelling
4	All of the following signs are evident and extensive	Pain along path of cannula Redness around site Swelling Palpable venous cord
5	All of the following signs are evident and extensive	Pain along path of cannula Redness around site Swelling Palpable venous cord Pyrexia

#### 4.12 Data Analysis

Data were analyzed using comparative statistical parameters (mean, median or mode) and their interpretative significance was verified using appropriate statistical tools (t-test, chi-square test etc). Microsoft Excel® and SPSS® software were used for data tabulation and analysis.

### 5. Observations and Results

#### 5.1 Randomization

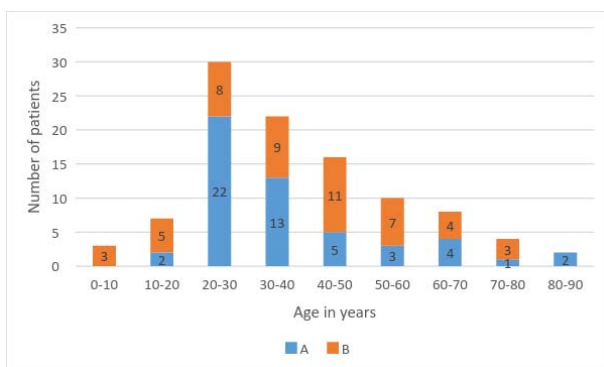
There were a total of 144 patients included who were initially recruited for the study. Subsequent to enrolment 42 patients had to be excluded due to development of any of the exclusion criteria. These left 102 patients whose data were included in the final analysis. This included 52 patients in group A and 50 patients in group B based on pre inclusion randomization.

#### 5.2 Patient Characteristics

##### 5.2.1 Age

The average age of the patients was 39.09 years ranging from 5 to 84 years with a median of 36. The averages in group A and group B were 37.98 and 40.24 respectively, the difference being statistically insignificant [ $p$  (t-test) = 0.260].

The differences in distribution of age between the two groups were statistically insignificant [ $p$  ( $\chi^2$ -test) > 0.05].



**Fig. 1** Age distribution among the two groups.

##### 5.2.2 Sex

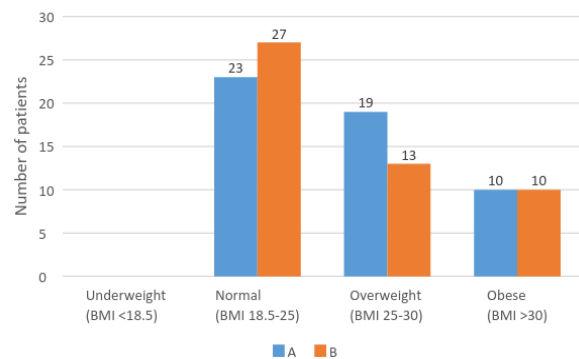
The overall M:F sex ratio was 0.85, being 0.68 in group A and 1.08 in group B. This difference occurred as a result of randomization but was statistically insignificant [ $p$  ( $\chi^2$ -test) > 0.05].



**Fig. 1** Sex distribution among the two groups.

##### 5.2.3 BMI

The mean BMIs in the two groups A and B were 25.85 and 25.30 respectively, being statistically similar [ $p$  (t-test) = 0.252] and close to the overall BMI of 25.58. None of the patients was underweight.



**Fig. 2** Distribution of BMI among the two groups.

##### 5.2.4 Co-morbidities

There were 8 patients with diabetes mellitus and 11 patients with hypertension overall. There were 4 diabetics that were same in both groups while there were 6 hypertensives in group A and 5 in group B. The differences were statistically insignificant [ $p$  ( $\chi^2$ -test) > 0.05].

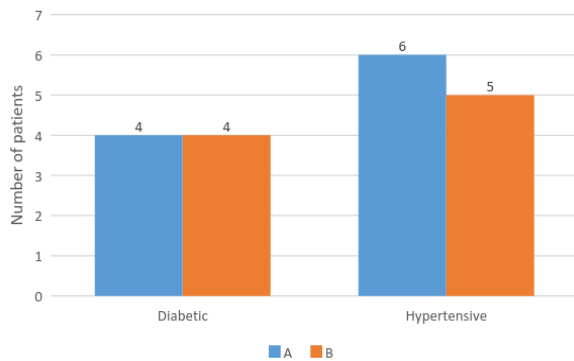


Fig. 4 Co-morbidities seen among the two groups.

### 5.2.5 Diagnosis

The patients were admitted for varied diagnoses as depicted in the chart below. Maximum number (31) of patients suffered from hepatobiliary or pancreatic pathology.

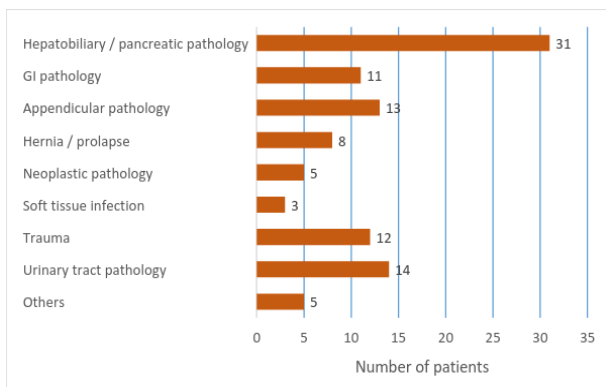


Fig. 3 The diagnosis.

### 5.2.6 Management

Of the 102 patients analyzed, 37 were managed conservatively (non-surgically). The 16 of these belonged to group A and 21 to group B. The remaining 65 patients were operated. Their distribution in the two groups is depicted below in the chart. Though the differences in the two groups were statistically significant [ $p$  ( $\chi^2$ -test) < 0.05], with a higher number of patients being operated in group A than group B, this occurred despite pre-decided randomization.

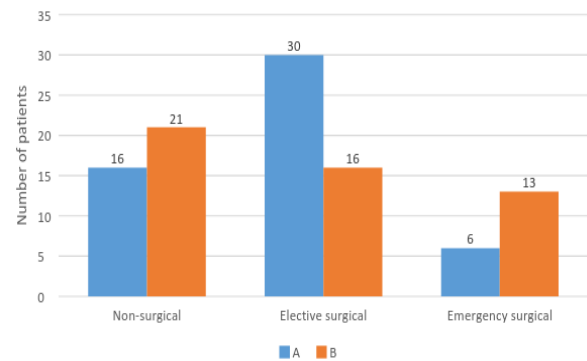


Fig. 4 Type of management administered to the patient among the two groups.

### 5.3 Outcomes

The primary outcome in terms of development of phlebitis was assessed using the VIP scale which had been detailed in the study proforma and taught to every assessor (doctors or nurses with at least 5 years of experience). Similarly pain was assessed using Visual analogue Scale for pain.

#### 5.3.1 Phlebitis

##### (1) Overall

The overall incidence of phlebitis was 62.75%, being 57.69% in group A and 68.00% in group B. The mean VIP score overall was 1.63, being 1.37 and 1.90 respectively in group A and B. This difference, though slight, turned out to be statistically significant [ $p$  (t-test) = 0.048] in favour of Group A.

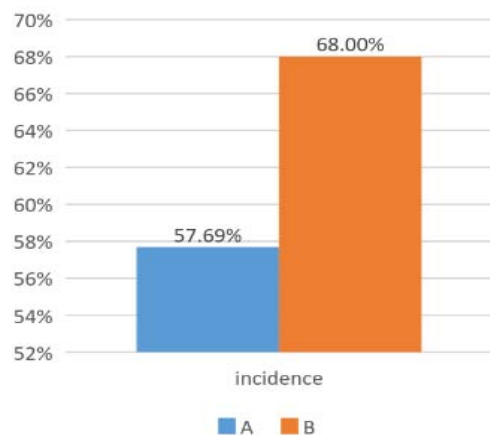
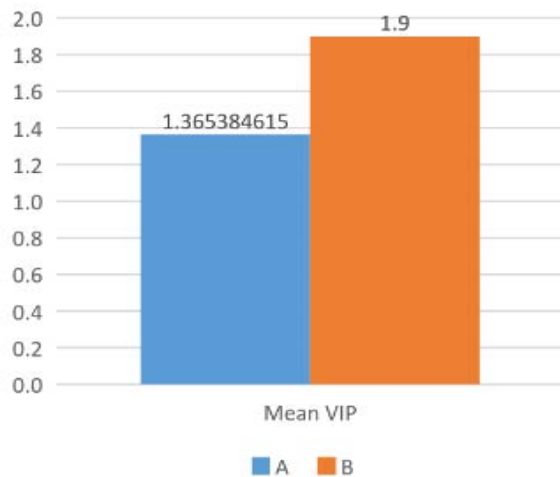


Fig. 5 Incidence of development of phlebitis in the two groups.

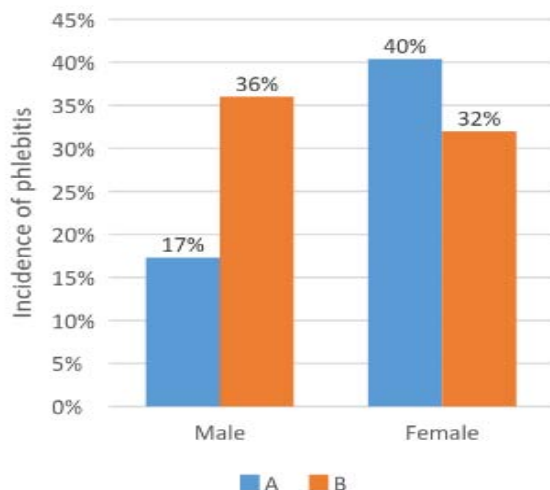


**Fig. 6** Mean VIP score among the two groups.

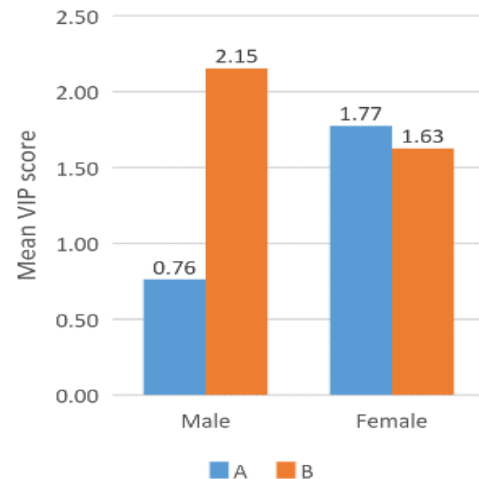
## (2) Sex

The incidence of phlebitis was higher in females compared to males overall. But males seemed to have better outcomes in group A as opposed to females who had slightly better outcomes in group B.

Mean VIP of males was 1.53 overall and 1.71 for females. The mean VIP was 0.76 and 2.15 respectively among males in group A and B. Females had lesser quantum of difference at 1.77 and 1.63 between the two groups. The differences between the two groups in case of males was statistically significant [ $p$  (t-test) = 0.001], while it was not in case of females [ $p$  (t-test) = 0.363].



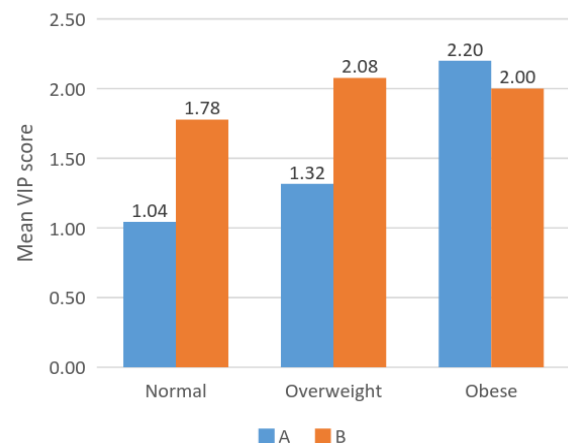
**Fig. 7** Association between the incidence of phlebitis and sex of the patients.



**Fig. 8** Association between the mean VIP score and the sex of the patients.

## (3) BMI

None of the patients were underweight. The mean VIP score tended to increase with BMI but the correlation was poor (Pearson correlation coefficient = 0.2).



**Fig. 11** Incidence of phlebitis among patients having different BMI.

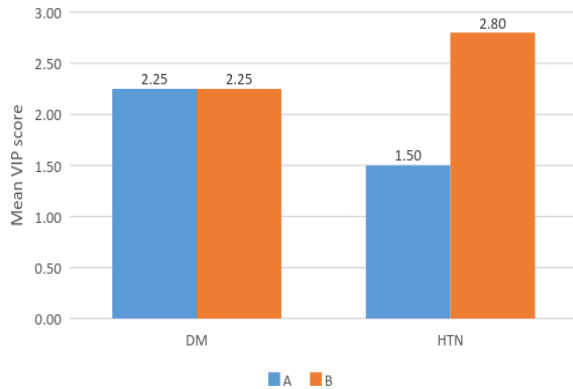
The differences in mean VIP between the two groups are statistically significant [ $p$  (t-test) < 0.05] in patients who have normal weight (BMI: 18.5-25) or who are overweight (BMI: 25-30). But the small difference of mean VIP in obese (BMI >30) patients is statistically insignificant [ $p$  (t-test) > 0.05].

## (4) Co-morbidity

The mean VIP score was identical among diabetic



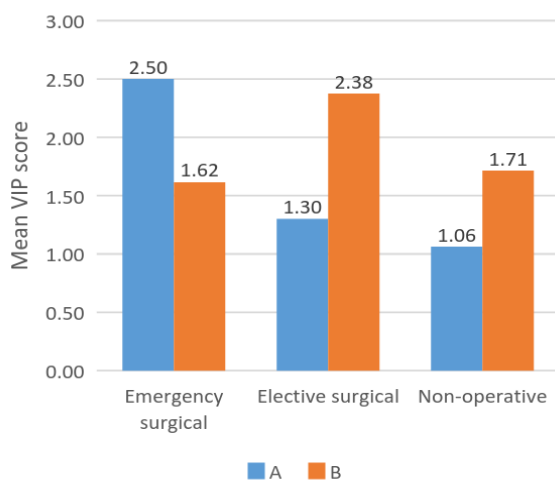
patients between the two groups. Among hypertensive patients, group A fared better with a mean VIP of 1.50, compared to 2.80 in group B. The difference in mean VIP among hypertensive patients of the two groups was statistically significant [ $p$  (t-test) > 0.05].



**Fig. 9 Development of phlebitis among patients of the two groups having different co-morbidities.**

#### (5) Type of Management

The type of management provided to the patient affected the degree of phlebitis as assessed by mean VIP. In emergency surgical cases routine elective change of IV catheter produced higher mean VIP of 2.50 compared to 1.62 if only need based change was done. This difference was statistically insignificant [ $p$  (t-test) = 0.1784].



**Fig. 10 Association between incidence of phlebitis and type of management of the patient.**

In case of elective surgery and non-operative

management, the VIP was lower in group A compared to group B. The differences in mean VIP of the two groups were significant only for elective surgical cases [ $p$  (t-test) = 0.0232]. The apparent benefit in non-operative cases was insignificant [ $p$  (t-test) = 0.1189].

#### 5.3.2 Pain

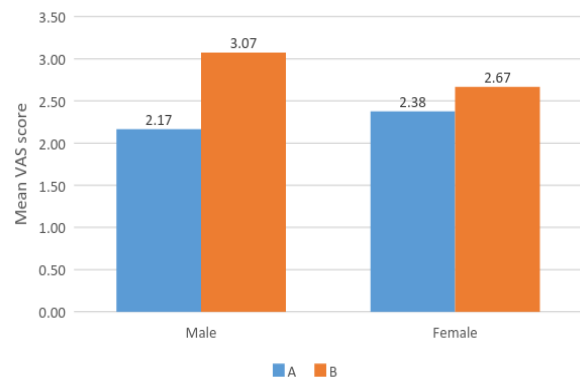
##### (1) Overall

The mean VAS score of pain at IV site or along the vein was 2.62, being 2.32 and 2.91 respectively in group A and B. These data only include those patients who had phlebitis (i.e. 22 out of 52 in group A and 23 out of 50 in group B).

##### (2) Sex

The perception pain was higher in males with a mean VAS score of 2.80 compared to females who have a mean VAS of 2.48.

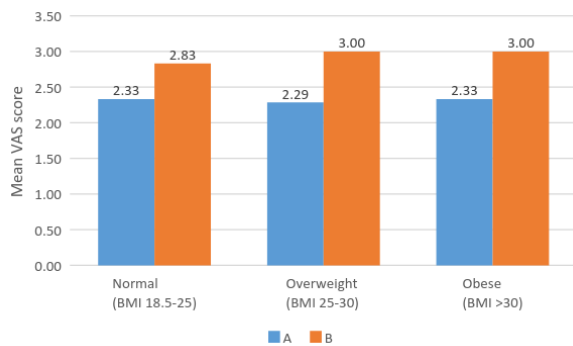
Between the two groups the mean VAS was higher for both males and female in group B as compared to group A. But the difference was significant for males [ $p$  (t-test) = 0.0275] while it was insignificant for females [ $p$  (t-test) = 0.1234].



**Fig. 11 Relation between incidence of pain and sex of the patient among the two groups.**

##### (3) BMI

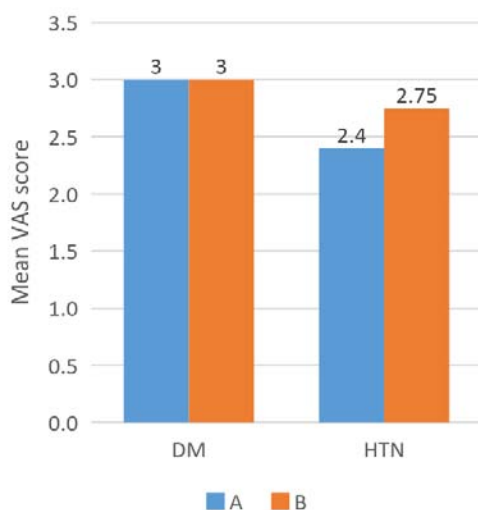
As depicted in the following graph, the BMI had little bearing on pain intensity perceived by the patient on development of infusion phlebitis. These differences between the two groups were statistically insignificant in the three subsets [ $p$  (t-test) = 0.052, 0.123 and 0.051].



**Fig. 12** Incidence of pain among patients of different BMI among the two groups.

#### (4) Co-morbidity

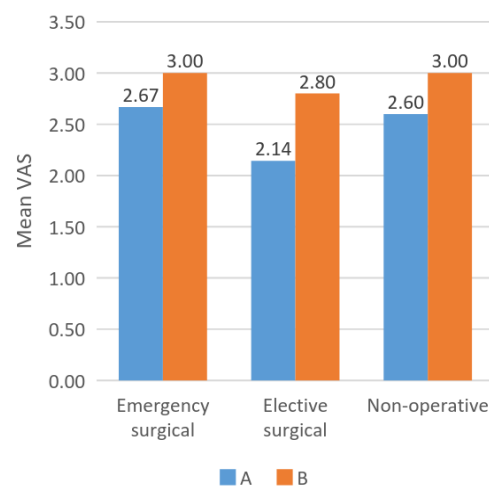
The pain intensity was identical in diabetic patients of the two groups, while among hypertensive patients it was lower in group A (2.40) compared to group B (2.75), but the difference was statistically insignificant [ $p$  (t-test) = 0.251].



**Fig. 13** Association between the mean VAS score and co-morbid conditions present in the patients among the two groups.

#### (5) Type of management

The mean VAS of pain at and along cannulation site was similar in the three subgroups based on type of management. VAS was slightly lower in group A in all three subgroups, with the difference between two groups (2.14 vs. 2.8) being significant in those patients who underwent elective surgery [ $p$  (t-test) = 0.046].



**Fig. 14** Association between the mean VAS score and the type of management administered to the patients among the two groups.

## 6. Discussion

### 6.1 Incidence of Phlebitis

The incidence of phlebitis in the current study was found to be 62.8%. This is higher than many previous studies, but may be due to stringent criteria used for defining phlebitis as per CDC guidelines and strict implementation of VIP scale for phlebitis assessment.

### 6.2 Association with Risk Factors

In the current, study age, gender, co-morbidities or BMI did not affect incidence of phlebitis. But the type of treatment meted out to the patient had a role, with emergency surgical patients having a higher incidence overall than conservatively managed or electively operated patients.

### 6.3 Timing of Catheter Change

Overall this study showed a slight advantage in electively re-siting the catheter every 24 hours. This advantage, though slight, is statistically insignificant. This is in contradiction to several previous findings and analysis, including the Cochrane review published this year.

The subset of patients who benefitted most is males, those undergoing elective surgery and hypertensive

patients.

## 7. Conclusion

Unlike most other studies, the current study has found a slight but significant advantage in electively re-siting IV catheter. This was most pronounced in males, hypertensives and those undergoing elective surgery.

## 8. Summary

A prospective comparative study was conducted in Department of Surgery, Central Referral Hospital situated in Gangtok and catering to a scanty local population. The study was carried out over a period of 2 months from 27-3-2015 to 29-5-2015. Of the 144 patients enrolled for the study, 102 were finally included for analysis. Among these 52 were randomized to group A (elective IV catheter change) and 50 to group B (need based catheter change). All patients were cannulated using a standardized protocol and identical make of the cannula was used.

Outcome assessment was done to assess phlebitis using the Visual Infusion Phlebitis scale and Visual Analogue Scale for pain. All assessors were sensitized to utilize these scales. The important findings of this study are:

- Incidence of phlebitis is high at 62.8%.
- VIP of patients in group A is slightly lower compared to group B (1.37 vs. 1.90) the difference being statistically significant.
- Among the various subsets the following seemed to benefit most if elective early cannula change:
  - Males
  - Hypertensive patients
  - Those undergoing elective surgery

## 9. Implications and Suggestions

Though the benefit provided by routine elective cannula change is statistically significant, it is slight. But this practice can be considered in case of hypertensive males posted for elective surgery.

A study with a larger sample size may be able to validate or these findings, and provide a guideline keeping in the local ethnic and regional variations in perspective.

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