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Original Research Article

Comparison between general anesthesia and thoracic spinal anesthesia in total laparoscopic hysterectomy

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ABSTRACT

Background and Aims: Total laparoscopic hysterectomy (TLH) is typically performed under general anesthesia (GA). However, thoracic spinal anesthesia (TSA) may serve as a valuable alternative, especially for high-risk patients. This randomized controlled trial aimed to compare the efficacy and safety of GA and TSA in patients undergoing TLH.

Materials and Methods: Sixty patients scheduled for elective TLH were randomized into group T (TSA) and group G (GA) of thirty patients each. Group G received conventional GA with intubation and mechanical ventilation while group T received TSA (sub-arachnoid block at T8/9 or T9/10 with hyperbaric levo-bupivacaine 0.5%, 0.7ml along with dexmedetomidine 4μg followed by isobaric levo-bupivacaine 0.5% 1.5 ml with dexmedetomidine 6μg μg in sitting position).Our primary aim was to compare the hemodynamic variations and secondary aim was to compare intra-operative and post-operative adverse effects and requirement of rescue analgesia between the two techniques.

Results: All 60 patients were analyzed for study. Group T patients showed greater hemodynamic stability with notably significant differences in mean SBP between the two groups after 30 minutes (at 40 minutes p=0.043, at 60 minutes p=0.007). The patients requiring rescue analgesia were significantly more in group G. Adverse events like intra-operative hypertension and post operative sore throat were more in group G.

Conclusion: TSA provides a safe alternative to GA for TLH with better hemodynamic stability, fewer side effects and lesser requirement of rescue analgesia.

1. Introduction

Total laparoscopic hysterectomies (TLH) are preferred over total abdominal hysterectomies as they involve decreased blood loss, shorter hospital stay, rapid recovery and fewer abdominal wall infections.[1–3] However the pathophysiological changes due to pneumo-peritoneum and Trendelenburg position on circulation and respiratory function pose challenges to anaesthesiologist. These surgeries are usually managed in general anesthesia(GA) with endotracheal intubation to prevent aspiration, respiratory embarrassment and shoulder pain caused due to pneumoperitoneum and Trendelenburg position.[4,5]

Neuraxial anaesthesia (NA) is beneficial in certain patients unfit for GA. Besides, GA has various drawbacks. Sympathetic stimulation during intubation and pneumo-peritoneum result in hypertensive episodes in patients which does not occur in NA. Moreover, NA results in better post operative analgesia.[6–8] However, conventional NA requires larger dose of local anesthetic (LA) leading to greater intra operative hypotension and at times inadequate relaxation due to unpredictable drug spread.

Thoracic spinal anaesthesia (TSA) is the performance of sub-arachnoid block at thoracic level. It provides effective

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and safe alternative to GA to combat all the challenges in TLH.[9,10] In TLH the dermatomes required to be blocked are quite extensive fromT-4 to S-5.For this we used a novel two drug technique(loaded in separate syringes) of spinal anaesthesia in sitting position. It comprises of injecting a 0.7 ml of hyperbaric LA (levo bupivacaine) followed by 1.5ml of isobaric LA (levo bupivacaine) in the thoracic sub-arachnoid space. Low dose of hyperbaric drug gives a dense block of thick sacral nerve roots and subsequent isobaric levobupivacaine blocks the T-4 to L-4 segments. Adjuvant dexmedetomidine is added to prolong the effect. Despite an extensive sympathetic blockade (T4 - S5), hemodynamic stability is maintained due the trendelenberg tilt and lithotomy position which maintain adequate venous return. Moreover, the isobaric LA at thoracic level gives greater hemodynamic stability as compared to hyperbaric. One ml of isobaric drug spreads approximately 2-3 segments above and below from the point of injection. Therefore the level of spread of an isobaric drug in thoracic sub arachnoid space can be predicted more accurately as compared to a gravity dependant spread of hyperbaric drug in lumbar sub arachnoid space in conventional spinal.[11]

Literature on alternative anesthesia techniques for total laparoscopic hysterectomy (TLH) is limited. Consequently, the primary aim of our study was to compare thoracic spinal anesthesia (TSA) with the standard technique of general anesthesia (GA) concerning hemodynamic variations. The secondary aim was to assess intraoperative and postoperative adverse effects, as well as the need for rescue analgesia in both techniques. We hypothesized that TSA would provide greater hemodynamic stability compared to traditional GA during TLH surgeries.

2. Materials and Methods

After an approval by Institutional Ethics Committee and a prospective registration with Clinical Trial Registry of India (www.ctri.nic.in) with registration number CTRI/2023/09/057798, our study was conducted in conformity with principles of the Declaration of Helsinki in a tertiary care medical centre from october 2023 to January 2024.

In this randomized controlled study, a total of 60 patients of ASA (American Society of Anesthesiologists) grade I/II undergoing total laparoscopic hysterectomy were randomly divided into two groups of 30 each with the help of computer generated randomization technique- Group S (receiving thoracic spinal anesthesia) and Group G (receiving general anesthesia).

Patients of age 40 and above, belonging to ASA grade 1 and 2 and gave written informed consent were included in the study. Exclusion criteria were patients with BMI>35 Kg/m^2 or with any contraindication for neuraxial block.

After obtaining written informed consent, patients were taken in operating room and ASA standard monitoring consisting of electrocardiogram, pulse oximetry, noninvasive blood pressure and capnography were connected. Baseline vitals were recorded. Intravenous access was secured for all patients with a 20 G three way cannula. All patients, irrespective of group, were preloaded with 10ml/kg ringer lactate in 15 minutes.. Intravenous (IV)ondansetron 4mg, glycopyrrolate 0.2mg and midazolam 1mg were given to all patients as premedication.

2.1. *Group S (Thoracic spinal anesthesia)*

Thoracic spinal anesthesia was administered in the sitting position under strict aseptic precautions at either the T8-T9 or T9-T10 interspace, depending on accessibility, using a 25 G Quinke spinal needle. After confirming free flow of cerebrospinal fluid, 0.7 ml of 0.5% hyperbaric levo-bupivacaine and 4 μg of dexmedetomidine were injected. This was allowed to settle for 30 seconds, after which 1.5 ml of 0.5% isobaric levo-bupivacaine with 6 μg of dexmedetomidine was administered through the same interspace. Patients were then positioned supine, and oxygen was delivered at 5 l/min via a Hudson mask.

The onset of sensory block was confirmed with a pinprick test, while motor block was assessed using the modified Bromage scale (0 – able to lift extended leg; 1 – able to flex knee; 2 – no knee movement but some ankle movement; 3 – complete lower limb paralysis). A sensory block up to T4-T5 was deemed optimal for commencing surgery. If the sensory block did not reach T4/T5, it was classified as a block failure, and general anesthesia was administered.

Vital parameters were monitored every minute for the first 15 minutes and then every 5 minutes until the end of surgery. Prior to carbon dioxide insufflation, patients received 30 mg of ketamine and 30 μg of fentanyl intravenously to alleviate discomfort from diaphragm stretching (C3, 4, 5 innervations via the phrenic nerve). Intraoperative adverse events, such as bradycardia, hypotension, and desaturation, were recorded and managed accordingly. Bradycardia (HR < 55) was treated with 0.6 mg of atropine IV, and hypotension (systolic BP < 80 mm Hg) was managed with 6 mg boluses of mephentermine and intravenous fluids. Intraoperative fluids used were Ringer's lactate at approximately 10-15 ml/min.

2.2. *Group G (General anesthesia)*

Patients in Group G received additional premedication with fentanyl (1.5 μg/kg IV), in addition to standard premedication common to both groups. Induction of anesthesia was achieved with propofol (2 mg/kg IV) until the abolition of the eyelash reflex. After confirming adequate bag and mask ventilation, atracurium (0.5 mg/kg IV) was administered to facilitate intubation after 180 seconds. Airway management was achieved using a 7 mm cuffed endotracheal tube, and patients were mechanically ventilated in volume control mode.

Maintenance of anesthesia included a 50:50 ratio of oxygen and air, isoflurane inhalation, and atracurium boluses. At the end of the procedure, neuromuscular blockade was reversed with neostigmine (2.5 mg) and glycopyrrolate (0.5 mg). Patients were extubated once spontaneous respiration was regained, and they could follow simple verbal commands.

Carbon dioxide was utilized for pneumoperitoneum, with intra-abdominal pressures maintained between 10-12 mm Hg at a flow rate of 5 l/min for all patients.

Post-operatively both group patients received diclofenac sodium 75 mg IV infusion and was subsequently repeated 8 hourly.Patients were shifted to PACU for further hemodynamic and pain monitoring and were shifted to the ward when the discharge criteria of PACU was met.These were mental alertness, stable vitals,absence of nausea or vomiting, control of pain.

Side effects recorded included incidence of intraoperative or post-operative hypertension(SBP>140 mm of Hg), hypotension (SBP<80 mm of Hg), nausea, vomiting, pruritis, shoulder pain, sore throat, headache, backache, urine retention, pain severe enough to require IV rescue analgesic (VAS 3) in first six hours. Acetaminophen infusion (500 mg) and tramadol 50 mg IV was used as rescue analgesic. Postoperative side effects were recorded and managed on day 0, day 1, day 2. Patients were discharged on day 3 if they fulfilled the discharge criteria.

Sample size was calculated using the formula $2(z\alpha + z\beta)^2\ (SD)^2 \div d^2$ from the results of a pilot study of 15 patients in each group. The value of mean SBP at 60 minutes of both groups yielded standard deviation (SD) =15.11. Difference between mean values (d)=10.63. Standard normal variate for level of significance ($Z\alpha$) =1.96 at 5% level of significance. Standard normal variate for power ($Z\beta$) =0.84 at 80% power. This yielded a sample size of 30 in each group.

Data analysis was done with IBM SPSS Statistics version 22. Data was processed on Microsoft Excel. Qualitative data was measured in percentages and proportions and were compared among groups using Chi square test. Quantitative data was measured as mean and standard deviation from mean (SD) and were compared by students t-test. Probability was considered to be significant if less than 0.005.

3. Results

Sixty patients were enrolled in this study. They were randomly allocated two groups —- Group G and group T of 30 each. All 60 had successful intervention and were analysed for study. (Diagram 1).

The study compared two groups, Group S and Group G, each with 30 participants, across various demographic and clinical variables, finding no significant differences. Ages, heights, and weights were similar between the groups, with p-values of 0.435, 0.340, and 0.433, respectively. Both groups also had similar distributions of American Society of Anesthesiologists (ASA) physical status classifications and durations of surgery, with p-values of 1.00 and 0.876, respectively. The prevalence of co-morbidities like hypothyroidism, hypertension, coronary artery disease, and anaemia also did not differ significantly (p-value of 0.496), indicating the groups were well-matched for further comparative analyses.(Table 1)

Table 1: Demographic data

Variable	Group S (n=30)	Group G (n=30)	p value
Age (yrs)	42.77±5.51	43.83±5.47	0.435
Height (cm)	154.80±6.66	156.20±4.37	0.340
Weight (kg)	58.00±4.84	58.93±4.31	0.433
ASA (I/II)	21 / 9	22/8	1.00
Duration of surgery (min)	104.67±31.15	106.00±33.28	0.876
Co-morbidity (Hypothy/HTN/CAD/Anaemic) *	3/8/0/2	4/9/1/0	0.496

*Hypothy = Hypothyroidism; HTN = Hypertension; CAD = Coronary artery disease

Table 2: Spinal data

Variable	Group S (n=30)
Space (T_{9-10} / T_{10-11} / T_{11-12})	9 / 19 / 2
Attempts (1/2)	26 / 4
Approach (Midline/ Paramedian)	17 / 13
Onset (minute) (mean±SD)	1.90±0.20

In Group S with 30 participants, the spinal procedure data showed a preference for the T10-11 space in 19 cases, followed by T9-10 and T11-12. Most procedures were successful on the first attempt (26 out of 30), and the approaches were nearly evenly split between midline (17) and paramedian (13). The average onset time was quick at 1.90 minutes (±0.20).

The Figure 1 presents a comparison of heart rate (HR) measurements between two groups, S and G, across various time points (0 to 150 minutes). The mean heart rate for Group S started at 92.70 bpm at 0 minute and fluctuate across time points, dipping to a low of 71.44 bpm at 130 minute before slightly increasing towards the end (while changing position from lithotomy to supine). For Group G, the mean heart rates begin at 97.67 bpm at 0 min and also vary, reaching a peak of 108.29 bpm at 150 min.

The T-test results, used to compare the mean heart rates between the two groups at each time point, show no statistically significant differences ($p > 0.05$) until 60min. Starting from 60 min, the p-values become increasingly smaller, indicating significant differences in heart rates

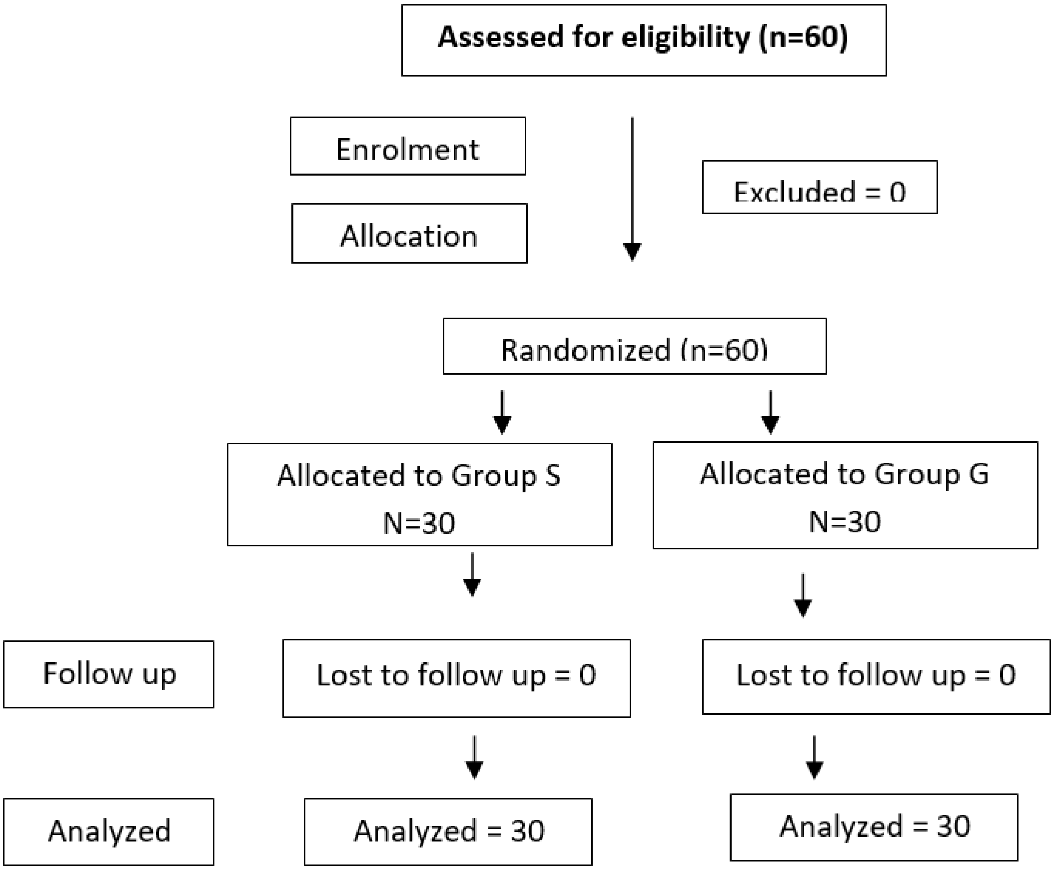

Diagram 1: Consort flow diagram

between the two groups at higher time points. Specifically, significant differences are observed at 90 min ($p = 0.006$), 110 min ($p = 0.002$), 120 min ($p = 0.001$), 130 min ($p = 0.007$), 140 min ($p = 0.043$), and 150 min ($p = 0.006$).

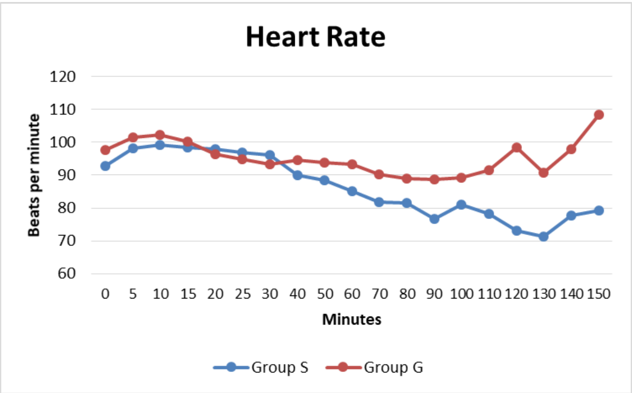

Figure 1: Variation in heart rate

T-test results comparing mean SBPs between the two groups at each time point, show no statistically significant differences early on ($p > 0.05$), specifically up to 25 min. However, starting from 30 min, significant differences begin to emerge at several time points. Notably, significant differences in mean SBPs between the two groups are observed at 40min ($p = 0.043$), 60min ($p = 0.007$), 70min ($p = 0.049$), 90min ($p = 0.016$), 110 min($p = 0.004$), 120 min ($p < 0.001$), 130 min($p = 0.032$), and notably at 150 min($p < 0.001$). (Figure 2)

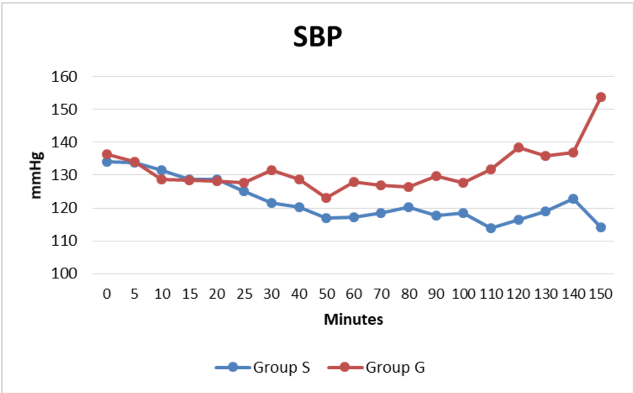

Figure 2: Variation in systolic blood pressure

T-test results assessing the mean differences in DBP between the two groups at each time point, largely show no statistically significant differences ($p > 0.05$) for most of the time points, indicating similar DBP levels between the groups. However, there are exceptions at 120 min($p = 0.004$) and 150 min($p = 0.028$), where significant differences are observed. (Figure 3)

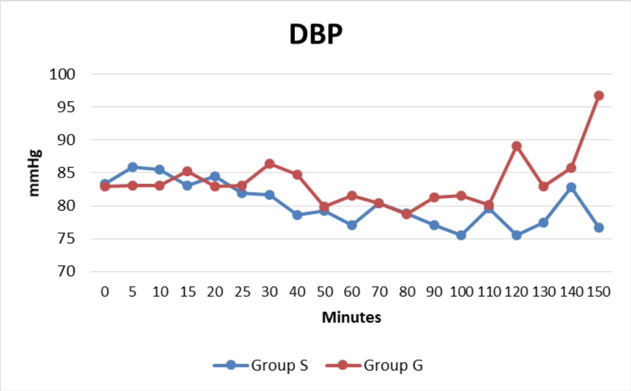

Figure 3: Variation in diastolic blood pressure

The statistical analysis of intraoperative and postoperative events between Group S and Group G revealed significant differences in certain areas, with p-values indicating less than 0.001 significance level for hypotension, abdominal pain post-operation, and the requirement for rescue analgesia. (Figures 4, 5 and 6). In Group S no patients required rescue analgesia. In group G, 17 patients required rescue analgesia and 13 did not require any rescue analgesic.

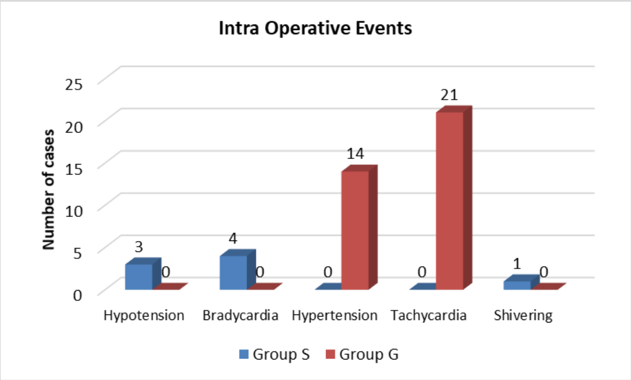

Figure 4: Intra operative events

4. Discussion

There are several factors leading to hemodynamic fluctuations in various phases of laparoscopic hysterectomies. The principal finding in this study showed that in Group G there was a fall in SBP and DBP during

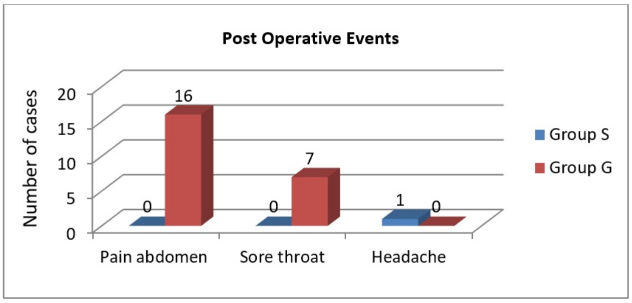

Figure 5: Post operative events

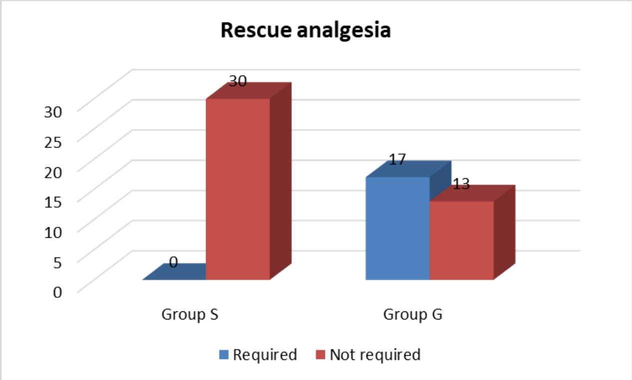

Figure 6: Rescuean algesia

induction phase followed by a rise during insufflation because of sympathetic response and further rise during lithotomy positioning and anti trendelenberg tilt because of increased venous return. An upward trend continued during the progression of surgery upto completion because of CO_2 absorption and surgical stress. Heart rate(HR) was more or less stable except a slight tachycardia when position was made from lithotomy to supine as compensation for the slight hypotension due to volume redistribution. As opposed to this, Group S showed an overall moderate dip in HR, SBP and DBP(within normal range) with stabile intra-operative hemodynamic state and lesser fluctuations because of more pronounced blunting of stress response to surgery. Slight dip was noted in SBP and DBP during restoration of supine position. In group S, three patients showed an episode of hypotension (as per our study definition) and four patients had bradycardia which was easily managed. In group G the incidence of intra operative hypertension (14) and tachycardia (21) was significantly more. Besides this, the incidence of post-operative sore throat and the requirement of rescue analgesia was significantly greater in group G. Group S patients were extremely comfortable post-operatively. There was no adverse neurological complication.

The occurance of profound hypotension that could have occured due to extensive sympathetic blockade in TSA for TLH (T4 to S4-5) is prevented by trendelenberg tilt and

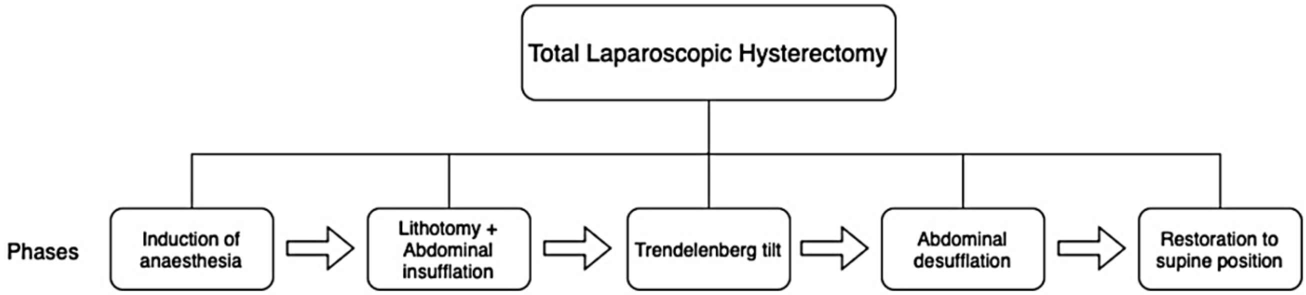

Figure 7:

lithotomy position in TLH. Adequate venous return in this position due to gravity despite the venous and arteriolar dialatation stimulates the chronotropic stretch receptors in right atrium and great veins. This maintains HR and cardiac output.[12,13]

With a trendelenberg tilt of just 10-15 degrees, the view and access of surgical field was not a problem because of meticulous preoperative mechanical bowel preparation which was followed by low residue diet. No conversion of TSSA case to GA was required.

Shoulder tip pain during or following laparoscopic surgery is a referred pain due to stretching of diaphragm by CO2 insufflation. The intra-peritoneal pressure after pneumoperitoneum in our study was set to 12mmHg, with flow rate of 5-6 l/min to avoid stretching of diaphragm. Central tendinous part of diaphragm has sensory relay to C3, C4, C5 via phrenic nerve which is spared in TSA. Review of literature reveals various methods that have been used to reduce shoulder tip pain like spraying bupivacaine on peritoneum under the diaphragm, using low pressure pneumoperitoneum (less than 10mmhg) etc.[6] In our study all TSA patients received ketamine 30mg and fentanyl 30μg during pneumoperitoneum stage to avoid shoulder discomfort intraoperatively.

Previous studies by Zundert et al have documented the uneventful use of TSA in patients with severe lung pathology. In this technique, even though the intercostal muscles of blocked dermatomes (T5-T12) are paralysed, patients have no respiratory discomfort. This is because the entire diaphragm, which is the key muscle for inspiration, receives its motor supply from C3, 4, 5 dermatome via phrenic nerve which is unaffected. The central respiratory drive is preserved in TSA, unlike GA, allowing the minute ventilation to adjust even to the absorbed CO2.[14–17]

TSA is performed above the termination of spinal cord above L1/L2. The major concerns are of hypothetical injury to spinal cord (SC), hemodynamic instability owing to blockade of cardio-accelerator fibres and respiratory issues that may arise due to paralysis of intercostal muscles. Going into each one, our first concern can be addressed by MRI studies which reveal how the SC sways within spinal canal from posterior at C5/6 to anterior position at T4-T10 and then again to a posterior position again at T12.[18] In 2010, Imbelloni and colleagues studied MRI of 50 patients in supine position. According to their study, at T2 the dura to cord distance (DTC) was 5.19mm, T5-7.75mm, T10-5.88mm.[19] Similar studies have been done by Park and colleagues. While performing TSA needle pierces duramater at 45degrees because of angulated thoracic spines. Therefore, the DTC is further increased. This explains the low incidence of neurological complications in TSA.[20]

Several studies in the past have described the safety and efficacy of TSA. In 2022, Roux et al defined the role of TSA in the 21st century in their review article, critically appraising all the available literature regarding TSA. The role of TSA becomes valuable in the subset of patients having specific risks for GA.[21]

Though several past studies have established the role of TSA in laparoscopic surgeries, its efficacy for TLH has never been studied. Our study has shows the comparison of TSA with the existing gold standard technique of GA. TSA fulfils the goals of anaesthetic management in TLH. Its advantages include fewer cardiac and respiratory complications and better suppression of stress response to surgery, minimal hemodynamic perturbations, better intra operative and post operative analgesia, early recovery of gastrointestinal and bladder functions, reduced incidence of postoperative nausea and vomiting, reduced blood loss during surgery, reduced cost and early discharge.[22–28]

There were however several limitations of our study. Our sample size of our study was very small and more randomised controlled trials on a heterogenous group of patients is required to validate the results of our study. Our study population did not encompass the general population as we excluded patients with high BMI, ASA 3 and 4, and patients with uterus size>14 weeks. This technique may also have limitation for surgeries with time stretching beyond two hours and may require a contingency plan of either a combined spinal epidural, a continuous spinal or GA. This should always be communicated with patient and surgeons.

5. Conclusion

Thoracic spinal anaesthesia is a safe and effective technique for TLH as it provides adequate sensory and motor block with minimal hemodynamic perturbations with reduced requirement of post operative analgesics. However, further randomised controlled studies in heterogenous cohort groups are required to establish the utility of this technique.

6. Source of Funding

None.

7. Conflict of Interest

Nil.

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