Efficacy of superior hypogastric plexus block with bupivacaine 0.5% for post total abdominal hysterectomy pain relief

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Abstract

Aim: To evaluate the analgesic effect of superior hypogastric plexus (SHP) area infiltration with 20 ml bupivacaine0.5% on post total abdominal hysterectomy (TAH) pain.

Patients and Methods: This a prospective randomized, double blind, placebo controlled study, conducted at Benha University Hospital, including sixty women undergoin TAH, thirty women received 20 ml bupivacaine 0.5% and thirty women received 20 ml saline infiltrated in SHP area at end of TAH. Main outcomes measures were total cumulative Nalbuphine consumption and post TAH pain using visual analogue scale (VAS), as well as nausea, vomiting, other analgesic requirements, time spent in post anaesthesia care unit (PACU), time to get out of bed.

Results: The mean post TAH pain VAS score at PACU, two, six hours postoperatively were significantly lower in bupivacaine group ($P = 0.016$, $P = 0.0006$, $P = 0.0008$). Total Nalbuphine consumption were significantly lower in bupivacaine group at six, twenty four hours, postoperatively and at discharge ($P < 0.0001$, $P < 0.0001$, $P < 0.0001$). Also total nonsteroidal anti-inflammatory drugs (NSAIDs) consumption were lower in bupivacaine at twenty four hours postoperatively as well as at discharge ($P < 0.0001$, $P = 0.0006$), nausea, vomiting, and time to first flatus were significantly lower in bupivacaine group ($P = 0.02$, $P = 0.02$, $P = 0.0068$).

Conclusion: Post TAH infiltration of SHP area with 20 ml bupivacaine 0.5% reduce postoperative pain and total cumulative opioid and NSAIDs analgesics as well as promotes early gut recovery after TAH.

Keywords: Total abdominal hysterectomy, visual analogue score, bupivacaine, local anaesthesia, opioids consumption.

Introduction

The most common major gynecological operation is hysterectomy and it's most common route is abdominal(1). The postoperative pain and discomfort is more pronounced and severe after total abdominal hysterectomy (TAH) than the others routes(1). To overcome the post TAH pain, womens usually need excessive amount of opioid analgesics which have several drawbacks as sedation, nausea, vomiting, inhibition of intestinal mobility and respiratory depression(2,3) as well as postoperative cognitive dysfunction in elder women and resulting delayed mobilization and rehabilitation(4). Thus opioid sparing analgesia is highly needed. The post TAH pain originates partially from visceral trauma to pelvic structures which are autonomically innervated and partially from somatic trauma to skin, subcutaneous tissue and muscles which are somatically innervated.

Researchers have been trialed several strategies to control somatic component of post TAH pain to lower the opioid consumption aiming in reducing opioid's side effects however there results are variables (5,6,7,8, 10,11,12,13,14,15).

Despite that the role of superior hypogastric plexus (SHP) – blocking in treating chronic pelvic pain is well studied(16 – 22), it's roll in controlling post TAH pain only trialed once(23) and the researchers reported, SHP- blocking with 20 ml ropivacaine 0.75% was significantly reduce post TAH cumulative opioid analgesics consumption(23). The aim of this work was to determine whether SHP – block (SHPB) done at end of TAH with 20 ml bupivacaine 0.5% could reduces postoperative pain and opioid analgesics consumption.

Patients and Methods

This prospective, randomized, double blind, placebo controlled clinical trial was done in obstetrics and gynecology department of Benha University Hospital, Alkalubia, Egypt from August 2016 to March 2017. The study protocol was approved by the local ethics committee and written informed consents were taken from participants entering the study. All women scheduled for TAH for benign indications between August 2016 and March 2017 were asked to participate. Exclusion criteria were allergy to either local anesthetics or opioids, daily consumption of pain killer's, fibromyalgia, ongoing treatment for depression, weight under 50 kg (Dose toxicity), dementia or mental retardation to a degree which would interfere with data collection.

Women were recruited sequentially and assigned to bupivacaine or saline at random in 1: 1 ratio. The study satiation created the randomized treatment allocation schedule by using a computer random number generator. The treatment allocation schedule was stored by the pharmacy and the point of randomization occurred when the study drug was ordered from pharmacy. The patients and clinical staff remained double blind until the study was completed.

Under standardized general anesthesia (including propofol as induction agent, pancurium as muscle relaxant, isoflurane as inhaltional anesthetic, Nalbuphine as an analgesic and neostigmine as muscle relaxant reverse, women were positioned and TAH was done in classic way, at end of the operation, the gynecologist inject, in the same fashion, the SHP area which situated anterior to L5-S1 vertebral bodies, Caudal to the bifurcation of the abdominal aorta with 20 ml of bupivacaine 0.5% or saline 0.9% retroperitoneally. Women were monitored for degree of sedation, hemodynamic and respiratory stability, pain, nausea vomiting at post anaesthesia care unit (PACU). The women were transferred to word when they were fully a wake and vitally stable. Nalbuphine HCL "Nalufin 20 mg/ml, Amonn pharmaceutical CO SAE. Elobour city, Cairo, Egypt" 20 mg was diluted in 20 ml saline and 5 ml (5mg) was given on women request if visual analogue scale (VAS) of pain $\geq$ 40 mm at rest at surgical ward and tenoxicom "soral 20 mg vial Global NAPI pharmaceutical industries for Global NAPI pharmaceuticals Egypt", 20 mg intravenously was given if women expressing pain on walking $\geq$ 40 mm on VAS at surgical ward.

The primary outcomes were postoperative consumption of Nalbuphine and postoperative pain assessed by VAS score ranging from 0 – to 100 mm, where 0 indicates no pain and 100 indicates the worst pain at PACU, 2, 6, 12, 24 hour postoperatively, while the secondary outcomes were presence of Nalbuphine – releated side effects such as nausea, vomiting, delayed bowel movement as well as delayed time to get out of bed, prolonged hospital stay and parental non steroidal anti-inflammatory drugs (NSAIDs) releated side effects.

Before starting this study, we evaluated the cumulative post TAH Nalbuphine consumption in Benha University Hospital, Obstetrics and gynecology Department and the average was found to be in prior 6 months, 52.5 $\pm$ (18.5) mg. Assuming $\alpha = 0.05$ and $B = 0.2$ (80% power) and using the two tailed student "t" test, 44 women were required to detect a 15.75 mg (30%) reduction in the mean cumulative Nalubuphine consumption, which was considered the minimal clinically significant effect by SHPB with bupivacaine 0.5% 20 ml. Regarding pain assessment, we assumed that the proportion of women with VAS estimated pain of $\geq$ 40 mm at 2 hour postoperatively would be 25% in treatment (bupivacaine) group and 63% in placebo (saline) group(23). 52 women would be need to reach a power of 80% in X2 test at significance level of 0.05%. Based on these calculations and to compensate for 20% drop out we decided to recrute 64 women.

Statistical analysis were by intention to treat and were performed by medcalc easy – to – use statical software for windows desktop (w.w.w.Medcalc.org) 2017 Medcale, software bvba(24). Categorical variables are presented in terms of frequencies and percents, while continuous variables are presented in terms of means, stander deviations and ranges. Student's t test for independent samples were used to compare continuous variables as baseline demographic and clinical criteria, amount of analgesia, operative time, visual analogue scale score and blood loss. Fisher's exact test was used to compare categorical variables as incidence of nausea, vomiting, and pruritis. P values and mean difference with 95% confidence intervals (CIs) were used to determine significance, $P < 0.05$ was considered statistically significant.

Results

In this trial, eighty women were assessed for eligibility; sixty four women were eligible and randomized to receive bupivacaine or saline, thirty two in each group. Four women didn't receive intervention, two in bupivacaine group and two in saline group due to necessity to do additional surgery other than simple TAH. Sixty women receive either bupivacaine or saline with thirty women allotted into each one and all sixty were included in the primary analysis (Figure I).

Women demographic and clinico-surgical criteria are presented in (Table I) and there were no difference between both groups.

Efficacy outcomes are presented in table (2,3,4). The post TAH pain with VAS score $\geq$ 40 mm at 2 hour postoperative (the prespecified primary outcome) were reduced by more than 38% (as in power calculation of this trial), with 20 ml bupivacaine 0.5% injected in area of SHP ($P \leq 0.0006$). In addition, post TAH pain at rest was significantly lower at PACU, 6 hour postoperatively in women receiving bupivacaine ($P = 0.0168$, $P = 0.0008$). While this intervention doesn't reduce pain at 12 hour, 24 hour at rest postoperatively as well as it doesn't reduce pain during movement significantly. The cumulative Nalbuphine consumption were significantly lowered by more than 30% (The prespecified main primary outcome) by injecting the SHP area with 20 ml bupivacaine 0.5% at 6h, 24h postoperatively as well as at discharge ($P < 0.0001$, $P < 0.0001$, $P < 0.0001$).

Also, this intervention successed to reduce significantly the 24 hour and at discharge post TAH cumulative NSAIDs ($P < 0.0001$, $P = 0.0016$) and time to first flatus ($P = 0.0068$) as well as reduce incidence of post TAH nausea and vomiting ($P = 0.02$, $P = 0.02$), but failed to reduce significantly time to get out of bed, PACU time and Hospital Stay.

No apparent complications related to bupivacaine 20 ml 0.5% injection into SHP area were noticed.

Fig. (I): Participant flow in the superior hypogastric plexus block (SHPB) trial.

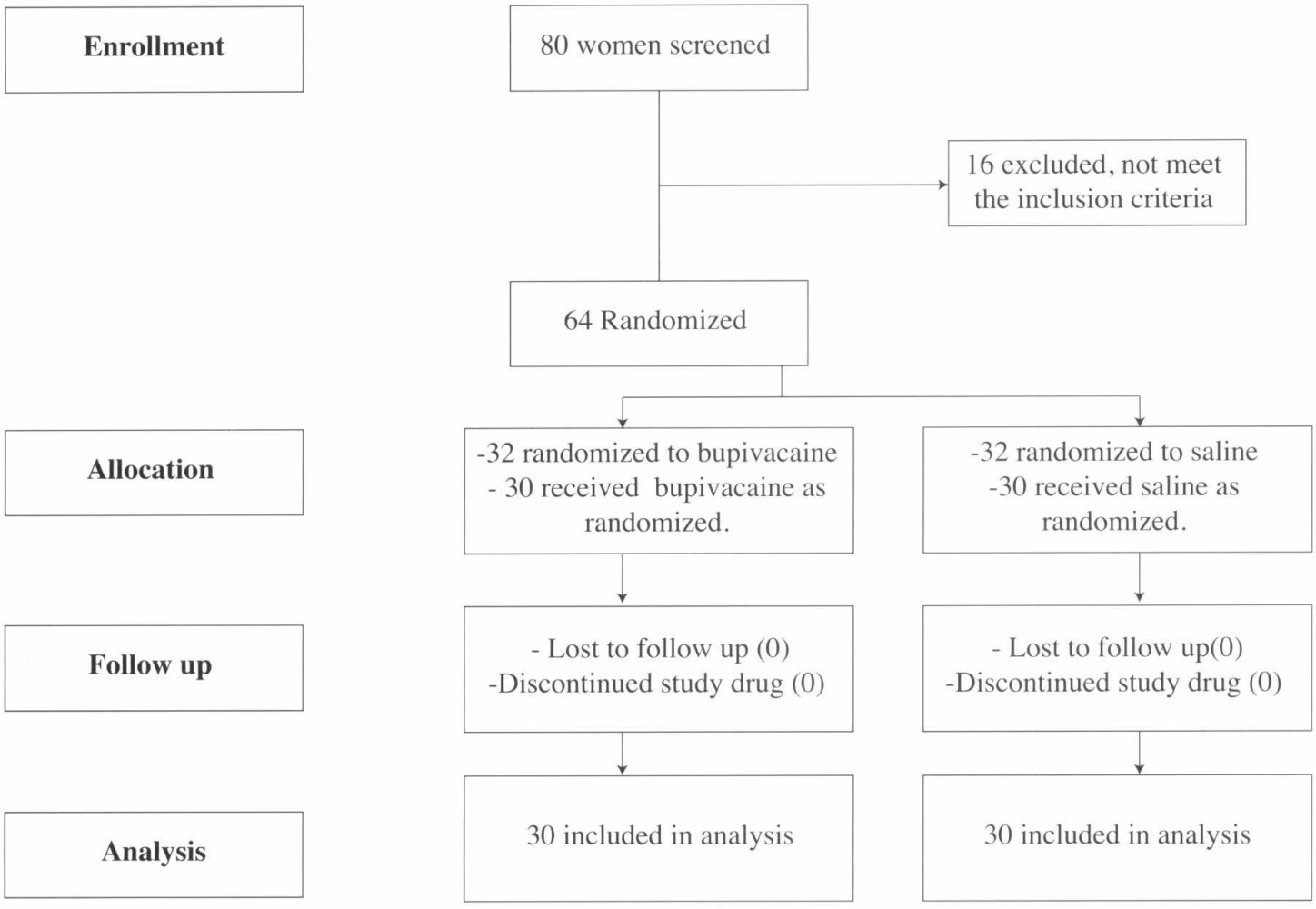

Table 1: Demographic and clinico-surgical criteria of women receiving bupivacaine or saline at end of TAH on SHPB trial.

Variable	Bupivacaine (n = 30)	Saline (n = 30)	P value
1- Age (year)*	48.3 ± 5.7 (43 – 62)	49.2±4.9(41-60)	0.51
2- BMI (kg/m2)*	30.2±4.2(24.2-38.5)	31.2±5.1 (23.8 – 38.7)	0.40
3- Indications of TAH** - PMB	16(53.3%)	15 (50%)	0.79
-Precancerous condition	3 (10%)	4(13.3)	0.71
- Fibroids	6 (20%)	7 (23.4%)	0.75
- Adenomyosis	5 (16.7%)	4 (13.3)	0.71
4- Concomitant comorbidity** - Diabetes	5 (16.7%)	6(20%)	0.74
- Hypertension	4 (13.3%)	3 (10%)	0.69
- Others	1 (6.7%)	2 (6.7%)	1
5- Uterine weight (gram)*	175 ± 50(90-350)	165 ± 60(80 – 400)	0.9
6- Operative time (min)*	115 ± 30(80 – 150)	120 ±25(75 – 150)	0.48
7-Estimated blood loss(ml)*	450 ± 80(350-750)	500 ± 130 (300 – 800)	0.07
8-ASA I/II	18/12	20/10	

Abbreviation: TAH : total abdominal hysterectomy, SHPB : Superior Hypogastric plexus block, BMI: Body mass index, PMB: Perimenopausal bleeding, ASA: American society of Anesthesiologists status.
- Values were given as mean ± standard deviation (range)* or number (percentage)**
- $P < 0.05$: statistically significant.

Table 2: Comparing pain during rest between women receiving bupivacaine or saline at end of TAH in SHPB trial.

VAS score (0 = non, 100 = worst)	Bupivacaine (n = 30)	Saline (n = 30)	Δ	95% C.I	P value
- PACU*	36 ± 12 (25 – 80)	46 ± 13 (30 – 90)	- 8	- 1.53 to – 14.46	= 0.016
- 2h*	36 ± 14 (30 – 80)	50 ± 16 (30 – 90)	- 14	- 6.23 to – 21.76	= 0.0006
- 6h*	40 ± 18 (30 – 80)	54 ± 12 (30 – 90)	- 14	- 6.09 to – 21.90	= 0.0008
- 12h*	45 ± 16 (35 – 85)	50 ± 18 (35 – 85)	- 2	-6.80 to + 10.80	= 0.65
- 24h*	46 ± 18 (35 – 85)	48 ± 16 (35 – 85)	- 2	- 6.80 to +10.80	= 0.65

Abbreviation: TAH: Total abdominal hysterectomy, SHPB: Superior Hypogastric plexus block, VAS: visual analogue scale score, PACU : Post anesthesia care unit. Δ : mean difference, 95% CI – 95% confidence interval.
- Values were given as mean ± standard deviation (range)*
- $P < 0.05$: statistically significant.

Table 3: Comparing pain during walking between women receiving bupivacaine or saline at end of TAH in SHPB trial.

VAS score (0 = non, 100 = worst)	Bupivacaine (n = 30)	Saline (n = 30)	Δ	95% C.I	P value
- 6h	48 ± 26 (40 – 90)	58 ± 30 (40 – 90)	- 10	- 4.50 to + 24.50	= 0.17
- 12h	50 ± 24 (40 – 90)	54 ± 32 (40 – 90)	- 4	-10.61 to + 18.61	= 0.58
- 24h	48 ± 30 (40 – 90)	54 ± 36 (40 – 90)	- 6	- 11.12 to + 23.12	= 0.48

Abbreviation: TAH: Total abdominal hysterectomy, SHPB: Superior Hypogastric plexus block, VAS: visual analogue scale score, PACU: Post anesthesia care unit. Δ : mean difference, 95% CI – 95% confidence interval.
- Values were given as mean ± standard deviation (range)*
- P < 0.05 : statistically significant.

Table 4: Comparing outcomes other than pain between women receiving Bupivacaine or saline at end of TAH in SHPB trial.

Outcome	Bupivacaine (n = 30)	Saline (n = 30)	Δ	95% CI	P value
- Time to get out of bed(h)*	5.8 ± 2.3 (4.5 – 8.5)	6.5 ± 3.2 (5 – 9.5)	- 0.7	-0.7 to + 2.1	0.33
- PACU time (min)*	58 ± 20 (40 – 110)	55 + 30 (40 – 110)	- 3	-16.17 to +10.17	0.65
- Hospital stay (h)*	65 ± 20 (40 – 96)	68 + 15 (38 – 96)	- 3	-6.13 to +12.13	0.51
- Time to first flatus (h)*	38 ± 6 (12 – 60)	42 ± 5 (14 – 65)	- 4	-1.14 to -6.85	0.0068*
- Nausea**	12 (40%)	21 (70%)	-30%	-2.56 to -53.10	0.020
- Vomiting**	7 (23.3%)	17 (56.6%)	-27.3%	-0.63 to -50.25	0.02
- Pruritis**	5 (16.6%)	9 (30%)	-13.4%	-10.73 to +35.69	0.22
-Post TAH cumulative Nalbuphine consumption (mg)* - at 6	24.7 ± 5.8 (10 – 50)	38.6 ± 6.5 (15 – 50)	- 13.9	-10.71 to -17.08	<0.0001
- at 24	30.8 ± 6.7 (10 – 60)	45.6 ± 7.5 (15 – 60)	- 14.8	-11.12 to -18.47	<0.0001
- at discharge	36.7 ± 6.2 (10 – 70)	55.6 ± 6.8 (15 – 70)	- 18.9	-15.53 to -22.26	<0.0001
- Post TAH cumulative parentral NSAIDs consumption(mg)* - at 24	26.6 ± 5.6 (20 - 40)	38.8 ± 6.6 (20 – 40)	- 12.2	-9.03 to -15.36	<0.0001
- at discharges	95.6 ± 20.8 (60 – 160)	115.6 ± 25.6 (80 – 160)	- 20.0	-7.95 to -32.54	= 0.0016

Abbreviation: TAH: Total abdominal hysterectomy, SHPB: Superior Hypogastric plexus block, VAS: visual analogue scale score, PACU : Post anaesthesia care unit. Δ: mean difference, NSAIDs: Non steroidal anti-inflammatory drugs, 95% CI : 95% confidence interval.
- Values were given as mean ± standard deviation (range)* or number (percentage)**
- P < 0.05 : statistically significant.

Discussion

The main target of immediate postoperative care is to minimize postoperative pain, nausea, vomiting and enhance early ambulation to prevent development of venous thromboembolism and pneumonia. There is advance in acute postoperative pain management from patient controlled opioid analgesia, but at risk of its side effects and from parentral NSAIDS with there abiliting to reduce postoperative dynamic pain[25].

The current study demonstrates that local infiltration of SHP area with 20 ml bupivacaine 0.5% is effective in achieving its pre specified primary outcomes including reduction of incidence of women with post TAH pain of VAS $\geq$ 40 mm at 2 hour postoperatively, in bupivacaine group 22/30 (73.3%) while in saline group 8/30 (26.6%) as well as control immediate PACU pain and this analgesic effect extended to 6 hour postoperatively. Also, SHPB with 20 ml 0.5% bupivacaine is effective in its main prespecified primary outcome which is a reduction of total cumulative post TAH nalbuphine consumption by 18.4 mg (33.9%) (36.6 vs 55.6 mg) as well as reduction of opioid releated side effects as the incidence of postoperative nausea (40% vs 70%), vomiting (23.3% vs 56.6%) is significantly lower in bupivacaine group and significantly shorting of postoperative gut recovery as it shortened time to flatus (38.6 vs 42.5 & P = 0.0068).

To the best of our knowledge, this is the second trial utilized SHPB in control of postoperative pain compared to placebo in women underwent TAH, but in this trial bupivacaine is used instead of ropivacaine used by **Rapp et al.**[23]. Similar results in controlling postoperative pain after TAH was reported by Rapp et al.(23) at 2 hour 25% of women with post TAH pain of VAS $\geq$ 40 mm in ropivacaine group versus 63% in saline group, but this effect isn't noticed by **Rapp et al.**[23] at immediate PACU and at 6 hour postoperative and this could be attributed to social and racial variation in the pain experienced by patients, anatomical variability of SHP[26] and several doctors performance of SHPB in **Rapp et al.**[23] trial but in this trial only two senior gynecologist performed the SHPB. Also **Rapp et al.**[23] reported success in reduction of post TAH total cumulative opioid consumption by 23% and this could be increase to significantly more higher level if one high outlier with opioid consumption in ropivacaine group, is excluded.

As opposed to the results of this trial, **Rapp et al.**[23] reported no difference in high opioid consumption related side effects as incidence of nausea, vomiting, and time to first flatus which may be attributed to high level routine word care in providing routine antiemetic as well as high level nursing care in developed countries where trial of **Rapp et al.**[23] was conducted. While significantly higher nausea and vomiting in placebo group in current trial may be explained by higher degree of post TAH pain and excessive consumption of Nalbuphine and parentral NSAIDs in the current study.

In contrary to many trials conducted to control post TAH pain with local anaesthetic infiltration[5, 6, 7, 10], the SHP area injection with local anaesthetic at end of TAH procedure has significant both opioid sparing effect as well as post TAH pain VAS scale reduction effect. As demonstrated in this trial and **Rapp et al.**[23] trial. The idea of infiltration of SHP area with local anaesthetic to control visceral component of post TAH pain is successful and the duration of post TAH pain control of SHP area infiltration with local anaesthetic could be prolonged more than 6 hour with either adding epinepherine 1 : 200.000 and increase in amount of local anaesthetic or utilizing more longer duration action local anaesthetic as liposomal bupivacaine[27].

This trial and **Rapp et al.** trial[23] showed that local anaesthetic infiltration of SHP area didn't reduce post TAH pain with walking and didn't resulted in early mobilization, a suggestion of infiltration of SHP prior to removal of uterus could reduce the surgical stress response which may in turn facilitate early mobilization[28, 29] and combination of SHP black with other effective local anaesthetic infiltration procedure as transversus abdominal plane block **(TAP)**[13], that control the somatic component of post TAH pain, could both effectively reduce post TAH pain and provide effectively opioid sparing analgesia as well as provide reduction of pain during walking which predominantly originate in skin, subcutaneous tissue as well as anterior abdominal wall muscle.

Conclusion

The present trial demonstrated the significant opioid sparing analgesic effect of SHP area infiltration with 20 ml bupivacaine 0.5% and reduction of well known excess opioid drawbacks as nausea, vomiting and delayed gut recovery after total abdominal hysterectomy as well as simplicity and absence of any squeal related to superior hypogastric plexus block.

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