Effect Of Ultrasound Guided Superficial Cervical Plexus Block Using Combination Of Bupivacaine And Lidocaine On Intraoperative Opioid Consumption In Tympanomastoid Operations In Adults, Randomized Controlled Study

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Abstract

Background
The study aims to detect impact of superficial cervical plexus block using combination of bupivacaine and lidocaine on intraoperative opioid consumption in adults ASA classification I-II in 20-45 years age group in tympanomastoid operations less than 4 hours.

Methods
Adult Patients belonging to ASA I-II in the age group 20-45 years, of either sex undergoing tympanomastoid operation under GA scheduled for operation time from 30 min to 4 hours.
90 Consenting patients will be randomly allocated to two groups, (S group n= 45) received GA without SCP block and (B group n= 45) received GA with SCP block.
The primary outcome is to record intraoperative opioid consumption .other outcomes include PONV incidence and severity over 24 hour, number of patients required rescue antiemetic, perioperative hemodynamics, postoperative pain (VAS),first analgesic request, ,side effects of drugs used and incidence of complications related to the block.

Results
Regarding total intraoperative fentanyl consumption in Group S was 181.11±28.78 while in group B was 162.22±26.45 so there was statistical difference between both groups (p value 0.002).
PONV incidence and severity were assessed at 5 time points during the perioperative period
When leaving the operating room (V0), there was statistical difference between both groups
(P value < 0.001).When leaving the post anaesthetic care unit (PACU) (V1) a period between 0 to 2 h postoperative, there was statistical difference between both groups (P value 0.002).
4 hours after leaving PACU (V2) a period between 2 to 4h postoperative, there was statistical difference between both groups (P value < 0.001).
8 hours after leaving PACU (V3) a period between 4 to 8h postoperative, there was statistical difference between both groups (P value 0.037).
24 hours after leaving PACU (V4) a period between 8 to 24h postoperative, there was no statistical difference between both groups (P value 0.245).
Regarding need for rescue antiemetics (ondanestron), there was significant statistical difference between two groups (p value <0.001). 34 patients (75.6%) received rescue antiemetics in group S while 14 patients (31.1%) received rescue antiemetics in group B.
Regarding need for postoperative analgesia (ketolac and pethidine), there was no significant statistical difference between two groups either regarding ketolac (p value 0.227) or pethidine (p value 0.830).There was no statistical differences between group S and B all over pain assessment times using VAS score it is may be due to subjective nature of the score and personal evaluation of each patient of pain severity.
There were no recorded perioperative complications related to the blocks in both groups.

Conclusion
Ultrasound guided superficial cervical plexus block using combination of bupivacaine and lidocaine reduce intraoperative opioid consumption in adults ASA I-II in 20-45 years age group of either sex undergoing tympanomastoid operations less than 4 hours.

List of abbreviations
SCP: Superficial cervical plexus, PONV: Postoperative Nausea and Vomiting, US: ultrasound, ENT: Ear ,Nose and Throat, IV ; Intravenous , VAS: visual analogue scale, PACU: post anesthesia care unit, SPSS: Statistical package for social science.

Key points

Question

Is SCP block reduce total intraoperative fentanyl consumption in adults undergoing tympanomastoid surgeries?

Finding

US guided SCP block reduce intraoperative opioid consumption in adults ASA I-II in 20-45 years age group of either sex undergoing tympanomastoid operations less than 4 hours.

Meaning

SCP block reduce intraoperative opioid consumption in tympanomastoid operations.

Keywords:

Ultrasound; SCP block; PONV; Postoperative ; Tympanomastoid surgeries.

INTRODUCTION

Pain and Postoperative nausea and vomiting (PONV) are common complications in most surgical operations, they are common causes of prolonged hospital stay and delay in patients' discharge and very distressing to them.[1]

When superficial cervical plexus (SCP) is blocked through its branches greater auricular and lesser occipital nerve, sensory innervations of the ear canal and inner ear will be lost that will contribute to reduce intraoperative opioid consumption , also the vagal afferent to area postrema is inhibited through afferent vagal input inhibition to the medullary center by block of auricular branch of vagus nerve (Arnolds' branch) at SCP that would be accidentally occur.[2]

SCP block may be used for intraoperative and postoperative analgesia in tympanomastoid operations that would also help to decrease PONV incidence as using local anesthetic will reduce opioids use to control postoperative pain and anxiety that considered important risk factors of PONV as they stimulate chemoreceptor trigger zone (CTZ) and slow gastric motility, also intraoperative pain control by SCP block will reduce consumption of intraoperative opioids, volatile anesthetics and NSAIDs which is important risk factor for gastric irritation and increase risk of PONV so proper pain management would help to decrease PONV incidence as there is a strong relationship between PONV and postoperative pain.[3–7]

Previous studies proved that bilateral SCP block is effective to reduce PONV incidence in thyroid operations, also US-guided greater auricular nerve block as a part of SCP or block of the plexus itself is useful for postoperative pain control in ear operations.[8]

This study aim was to identify SCP block effect on intraoperative fentanyl consumption in tympanomastoid surgeries.

Methods:

The study included adult's American society of anesthesiology physical status I, II, aged 20 to 45 years of both sexes presented for tympanomastoid operation under GA scheduled for operation time from 30 min to 4 hours at ENT operating theatres, Cairo university hospitals 90 Consenting patients were randomly allocated to two study groups S group 45 patients received GA without SCP block and B group 45 patients received GA with SCP block (figure 1).

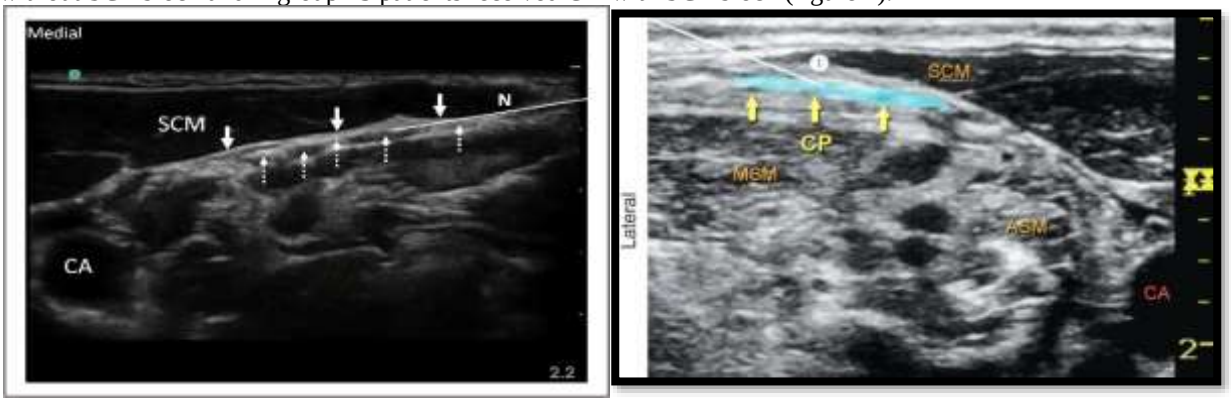

Figure 1 : US guided SCP block

Inclusion criteria

- Patients belonging to American Society of Anesthesiologists physical status I-II.
- Age group 20-45 years.
- Female or male.
- Operation time less than 4 hours.

Exclusion criteria

- American Society of Anesthesiology (ASA) physical status ≥ III.
- Uncooperative or mentally retarded patients.
- Known Allergy or hypersensitivity to lidocaine or bupivacaine.
- Patients known to have gastritis or Gastro-oesophageal reflux disease (GERD).
- History of PONV or motion sickness.
- Operation duration (short less than 30 minutes or prolonged more than 240 min).
- Patients with chronic renal disease (serum creatinine level ≥2.0mg/dl) or on renal replacement therapy (dialysis).

- Patients with chronic cholecystitis (history of recurrent or persistent vomiting)
- Skin inflammation and cellulitis.

Before start of anesthesia, envelopes were opened by a research assistant who was not involved in the study. The instructions were given to the attending anesthetist performing the block who was not involved in the data collection.

The patient attended at the pre-anesthesia room 1 hour before the procedure. A 20 Gauge cannula was inserted peripherally. Prophylactic antiemetic (metoclopramide 0.15mg/ kg) was given slowly IV as premedication.

In the operative room, standard monitoring (electrocardiography, pulse oximetry, non-invasive blood pressure and capnography after intubation) was applied to the patient.

GA induction was performed with intravenous propofol 2 mg/kg , fentanyl 2 mcg/kg, atracurium 0.5 mg/kg and the trachea was intubated after mask ventilation for 3 minutes.

Anesthesia was maintained with IPPV, isoflurane (MAC 1-1.5) in oxygen/air and atracurium 0.1mg/kg as a neuromuscular blocker by time every 20 minutes.Ventilation was controlled to maintain an end-tidal CO2 at 30-35 mmHg. After GA induction and in supine position, patient head was turned to the opposite site of the side of the block to be applied, the area was disinfected with povidone iodine, In Group B superficial cervical plexus block was done using high frequency linear ultrasound probe in transverse position (**Mindray Digital Ultrasounic Diagnostic Imaging System, *Model DP-10 "SN 6N-49005130" 2014-09. SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.LTD***.) to visualize the SCP posterior to the midpoint of the SCM muscle.

The transducer probe **(mindray, made in china, model 75L38EB. 2016-08.SN:AGC66121780)** was shifted posteriorly and the prevertebral fascia and SCP (in the form of small hypoechoic nodules) was seen under the SCM muscle Once identified, it was blocked using a 20-22 gauge B-bevel needle (Stimuplex Ultra 22 Gauge x 2 inch Echogenic Needle) ,combination of 5 ml bupivacaine (0.5%) , 5 ml lidocaine was prepared total volume injected was 10 ml after negative aspiration followed by injection of 1 ml bupivacaine to confirm the area and avoid intravascular injection.

In Group S, 10 ml normal saline injected at the same site of block described before in group B as a control group.

In case of signs of lack of intra operative analgesia (tachycardia & hypertension > 20% of baseline) additional 0.5 ug/kg fentanyl top up doses was given and recorded to calculate total opioid consumption in each group.

Bradycardia was defined as HR less than 50 beats /min and treated with 0.01 mg/kg atropine intravenous injection and patient excluded from the study.

At the end of the procedure, residual neuromuscular block was antagonized with atropine 0.01 mg/kg and neostigmine 0.05mg/kg , extubation and suction under vision was done .

Heart rate, non invasive blood pressure, oxygen saturation were continuously measured and recorded every 15 minutes at times baseline (T0), post induction (T1), after block given(T2), every 15 minutes until operation end (T3,4,5,...up to 4 hours) till the end of surgery and postoperative on arrival of post-anesthesia care unit.

PONV incidence was assessed at 5 time points during the perioperative period, first when leaving the operating room, second when leaving the post anaesthetic care unit (PACU), third 4 hours after leaving PACU, fourth 8 hours and finally 24 hours after discharge.

Rescue antiemetic (ondanestron 0.15mg/ kg) was given slowly intravenously if more than two episodes of nausea, and/or vomiting had occurred or the patient had persistent nausea.

Visual analogue score was used for the assessment of postoperative pain from 0 to 10 according to severity of pain at 6 times Postoperative pain in recovery , 2 hours, 4hours , 8 hours , 12 hours, 24 hours postoperative (P5).

In the recovery room, postoperative first analgesic request time was recorded, all patients received intravenous1000 mg acetaminophen every 6 hours for 24 hours as analgesic if visual analogue score ≥4 if pain was still persisting, intravenous 30mg ketolac was diluted in 20 ml saline and will be given slowly, if pain was still persisting and VAS ≥4, 0.5mg/kg intravenous pethidine was diluted in 20 ml saline and given slowly.

The patient was discharged to the ward according to Post anesthetic Aldrete recovery score.

The primary outcome is to record total intraoperative opioid consumption.

Secondary outcomes included PONV incidence over 24hour postoperative grades 1, 2 and 3 according to scoring system(grade 0 No nausea, no vomiting, grade 1:Nausea present, no vomiting, grade 2: Nausea present, vomiting present, grade 3: Vomiting>2 episodes in 30 minutes, number of patients required rescue antiemetic , Postoperative pain immediate in recovery, 2nd, 4th, 8th, 12th and 24th hours postoperative by visual analogue score (VAS),Need for postoperative analgesia (first analgesic request), hemodynamics (blood pressure and heart rate) at pre-induction (base line), post induction, after regional ear block , intraoperative and postoperative, Side effects and toxicity of drugs (local anaesthetic lidocaine-bupivacaine) e.g allergy, convulsions, hypotension and complications of regional ear block (hematoma-facial nerve palsy-oedema).

Sample size:

Based on previous study[9], using MedCalc Software version 14.10.2 (MedCalc Software bvba Ostend ,Belgium), we calculated a minimum sample size of 84 patients to have a study power of 80% and alpha error of 0.05.The number will be increased to 90 (45 in each group) patients to compensate possible dropouts.[9]

Statistical analysis:

IBM SPSS statistics (v. 22.0, 2013; IBM Corp., Chicago, Illinois, USA) was used for data analysis. Data was expressed as mean ± SD for quantitative parametric measures in addition to median percentiles for quantitative nonparametric measures and both

number and percentage for categorized data. Comparison between two independent mean groups for parametric data was done using Student's *t*-test. $\chi 2$-Test was used to study the association between two variables or comparison between two independent groups with regard to the categorized data. The probability of error at or below 0.05 was considered significant, whereas the probability at 0.01 and 0.001was considered highly significant.

Results:

This study covers patients with ASA I-II between the ages of 20 and 45 years, of either sex, who are planned to undergo tympanomastoid surgery under GA for duration of 30 minutes to 4 hours.

90 consenting patients were assigned to one of two study groups at random: group (S):45 patients were given GA without the use of a SCP block (only saline was injected as control) and 45 patients in group (B) were given GA with SCP block.

Demographic data and baseline characteristics (age, sex and operation time) were comparable between both study groups with no significant statistical difference as shown in table 1.

		Group S		Group B		P value
		Mean	SD	Mean	SD	
Age		31.44	8.13	32.64	8.08	0.484
Operation time min		115.00	34.00	118.33	34.62	0.646
		Group S		Group B		P value
		Count	%	Count	%	
Sex	Male	27	60.0%	22	48.9%	0.290
	Female	18	40.0%	23	51.1%	

Regarding total intraoperative fentanyl consumption in Group S was 181.11±28.78 while in group B was 162.22±26.45 so there was statistical difference between both groups **(p value 0.002)** as shown in table 2.

Table 2 Total intraoperative fentanyl consumption in both groups

	Group S		Group B		P value
	Mean	SD	Mean	SD	
Total fentanyl consumption	181.11	28.78	162.22	26.45	0.002*

In Group S, 19 patients (42.2%) consumed dose of 150 µg, 24 patients (53.3%) consumed dose of 200 µg and 2 patients (4.4%) consumed dose of 250 µg.

In Group B, 2 patients (4.4%) consumed dose of 100 µg, 30 patients (66.7%) consumed dose of 150 µg, 13 patients (28.9%) consumed dose of 200 µg.So there was statistical difference between both groups **(p value 0.008)** as shown in table 3 and figure 2.

Table 3 :Number and percentage of patients received introperative fentanyl and differences between both groups and dose consumed.

		Group S		Group B		P value
		Count	%	Count	%	
total fentanyl dose (µg)	100	0	0.0%	2	4.4%	0.008*
	150	19	42.2%	30	66.7%	
	200	24	53.3%	13	28.9%	
	250	2	4.4%	0	0.0%	

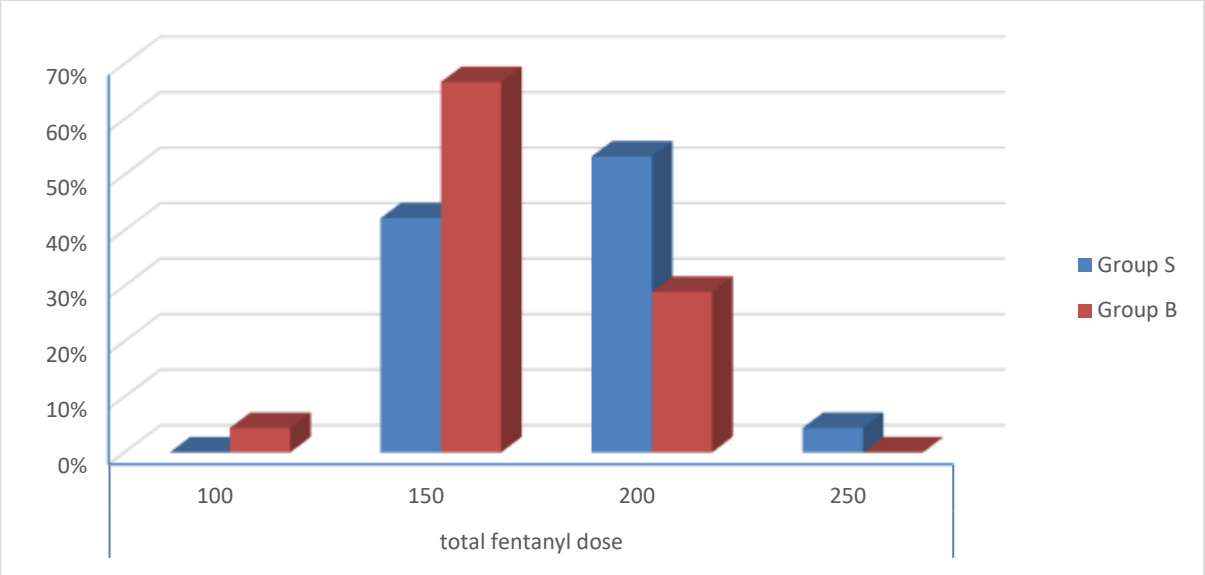

Figure 2 Number and percentage of patients received intraoperative fentanyl dose consumption

PONV incidence and severity were assessed at 5 time points during the perioperative period, When leaving the operating room (V0), there was statistical difference between both groups
(P value < 0.001), when leaving the post anaesthetic care unit (PACU) (V1) a period between 0 to 2 h postoperative, there was statistical difference between both groups **(P value 0.002)**.
4 hours after leaving PACU (V2) a period between 2 to 4h postoperative, there was statistical difference between both groups **(P value < 0.001)**, 8 hours after leaving PACU (V3) a period between 4 to 8h postoperative, there was statistical difference between both groups **(P value 0.037)**,24 hours after leaving PACU (V4) a period between 8 to 24h postoperative, there was no statistical difference between both groups **(P value 0.245)**.
Regarding need for rescue antiemetics (ondanestron), there was significant statistical difference between two groups **(Pvalue <0.001)**.
There was no statistical differences between group S and B all over pain assessment times using VAS score postoperative, it is may be due to subjective nature of the score and personal evaluation of each patient of pain severity.
Regarding need for postoperative analgesia (ketolac and pethidine), there was no significant statistical difference between two groups either regarding ketolac **(P value 0.227)** or pethidine
(P value 0.830).
Regarding Heart Rate, there was statistical differences between group S and B as P value was significant at baseline before anesthesia induction (T0) **(P value 0.003)**, post induction (T1) **(Pvalue 0.030)**, after block given (T2) **(P value 0.018)** but this difference has no clinical significance.
Regarding MAP, there was no statistical differences between group S and B.
There were no recorded perioperative complications related to the block in both groups.

Discussion:

90 participants with informed consent were randomly assigned to one of two groups: Saline Group (S) 45 patients underwent GA without SCP block (control group) and 45 patients underwent GA with US guided SCP block in group (B) using combination of 5 ml bupivacaine (0.5%), 5 ml lidocaine in group B and 10 ml saline in group S as controlled group.
Regarding intraoperative analgesic consumption, our study concluded that there was statistical difference between both groups (**p value 0.002**) as total intraoperative fentanyl consumption in Group S was **181.11 ± 28.78** while in group B was **162.22±26.45 .**
In agreement with our study, Eti et al, detected that bilateral SCPB with bupivacaine delivered before surgical incision decreased perioperative fentanyl consumption, in addition **H-D Cai et al**, concluded that intraoperative fentanyl consumption in ropivacaine group **158±31** which is lower than saline controlled group **208± 49** (**P <0.001**).
Regarding PONV, our study reported that PONV incidence and severity were assessed at 5 time points during the perioperative period.
Using PONV score grading 0,1,2 and 3 and there was statistical difference between both groups when leaving the operating room (**P value < 0.001**), 2 h (**P value 0.002**), 4 h (**P value < 0.001**), 8 h postoperative (**P value 0.037**).While there was no statistical difference between both groups (**P value 0.245**) 24 hours postoperative.
There was statistical difference between group S and B regarding grade 1 of PONV score (mild) (**P value 0.041**) and grade 2 (moderate) (**P value 0.038**) all over 24 hours (0-24h).
In agreement with our study, H-D Cai et al, included **140** patients **68** in saline group and **67** in ropivacaine group (5 was excluded 4 difficult intubation and 1bleeding postoperative).

It concluded that anatomical blind technique of bilateral SCPB with 10 ml ropivacaine 0.5% given prior to surgical incision could reduce PONV incidence and early postoperative pain and perioperative opioid requirements in thyroidectomy operations. PONV incidence was lower in ropivacaine than saline group and there was statistiacal difference between two groups at time periods 0-4h (**P value =0.001**), 4-24h (**P value < 0.001**).0-24h (**P value < 0.001**). However this study had three differences from our study ;local anaesthetic used (ropivacaine not bupivacaine), anatomical technique of block performance not ultrasound guided and it was bilateral (not unilateral).[10]

While in disagreement with our study, **Eti et al**, concluded that incidence of nausea was **53.3** percent in patients who had bilateral SCPB and **73.3** percent in those who did not get a regional block; vomiting occurrences were **13.3** percent and **26.6** percent, respectively. These differences, however, were not statistically significantly different between the groups, which may be due to the small number of patients included in the study (**n = 15**).[11]

Regarding need for rescue antiemetics, in our study, there was statistical difference between two groups (**p value <0.001**). **34** patients (75.6%) received rescue antiemetics (ondanestron) in group S while **14** patients (31.1%) received rescue antiemetics in group B.

In agreement with our study, H-D Cai et al, concluded that need for rescue antiemetics in ropivacaine group was lower than saline group (**P value 0.010**). [10]

Regarding Postoperative pain and analgesic requirements, Postoperative Pain was assessed by VAS at 6 times immediate in recovery (**P value 0.320**), 2h (**P value 0.427**), 4h (**P value 0.811**), 8h (**P value 0.731**), 12h (**P value 0.736**), 24h postoperative (**P value 0.945**), while regarding postoperative analgesic consumption, we found that **36** patients (**80%**) in group S and **31** patients (**68.9%**) group B received ketolac while **19** patients (**42.2%**) in group S and **18** patients (**40%**) received pethidine in group B, there was no significant statistical difference between two groups either regarding ketolac (**P value 0.227**) or pethidine (**P value 0.830**), this may be explained by small sample size and subjective nature of VAS score.

In agreement with our study, Shih et al, concluded that patients in bupivacaine (B) and levobupivacaine (C) groups required fewer analgesics (**P= 0.001**), and it took longer for the first postoperative analgesic dose to be required (**P=0.001**) than saline group. For the first 24 hours postoperatively, however VAS scale for postoperative pain was lower in groups B and C (**P=0.001**) unlike our study that may be due to different drugs and doses used.[12]

In agreement with our study, Korgün ÖKMEN et al, reported that SCP and GAN blocks using bupivacaine are effective in pain control after tympanomastoid surgery.Pain assessed by VAS at 5 times (Immediate postoperative, 2nd, 4th, 6th, 12nd and 24th) hour postoperative and tramadol consumption at (6th, 12nd and 24th), also PONV as side effects as a secondary outcome.There was no statistical difference regarding VAS pain score in all times as our study.

While in disagreement with our study, regarding postoperative opioids consumption in our study we used pethidine while **Korgün ÖKMEN et al,** used tramadol and there was reduced tramadol consumption in SCP block group in comparison to GAN block group (**P value 0.002)** at 6h, (**P value 0.001**) at 12h, (**P value 0.003**) at 24h.There are two explanations for reduction of tramadol consumption found in the SCP group; better analgesia in the ear region due to lesser occipital nerve block which is a branch of SCP and contributing to the sensation of ear posterior. The second reason may be volume of local anaesthetic that the volume of 10 ml used in SCP block may have provided a longer blockade than 5 ml volume used in GAN. However ,this study had two limitations differences from our study ; small sample size (25 in each group) and there is no control group.[13]

In disagreement with our study, H-D Cai et al detected that VAS score was lower in ropivacaine group than saline controlled group at 0, 4 and 8h (**p<0.05**) while no significant difference at times 12, 16 and 24h postoperative.[10]

Previous studies include **Aunac S et al , Dieudonne N et al and Andrieu G et al** reported that local anaesthetic wound infiltration, bilateral SCPB and bilateral combined superficial and deep cervical plexus block could reduce postoperative opioid requirements but these studies were not designed to evaluate the PONV incidence as an outcome,however our study didn't observe significant statistical difference between two groups regarding postoperative opioids consumption**,**.[14–16]

Regarding complications, In our study, no complications allergy-fits-hematoma-facial palsy) were detected in both groups and we did not detect complications similar to those in the literature, this may be due to relative small sample size of patients and using of ultrasound in block performance.

In disagreement with our study, H-D Cai et al, reported occurrence of Horner syndrome in 12 cases in ropivacaine group and disappeared 4h after surgery ,this complication may be due to blind technique of block and use of different local anaesthetic.[10]

Study limitations:

Drawbacks and limitations of our study include small sample size, few articles discussed effect of regional block or local infiltration on PONV in direct way as primary outcome not as a side effect, pain assessment tool (VAS score) is subjective tool may depend on own patient evaluation of feeling pain.

Conclusion:

We concluded that ultrasound guided superficial cervical plexus block using combination of bupivacaine and lidocaine reduce intraoperative opioid consumption and PONV incidence and severity in early postoperative period and decrease need for postoperative rescue antiemetic in adults ASA I-II in 20-45 years age group of either sex undergoing tympanomastoid operations less than 4 hours.SCP block was safe, and no perioperative complications were encountere.

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