Original Research Paper

Volume - 12 | Issue - 08 | August - 2022 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

TO EVALUATE THE EFFECT OF 0.2% ROPIVACAINE MOISTENED V/S NORMAL SALINE MOISTENED DRESSINGS ON POSTOPERATIVE PAIN RELIEF AT DONOR SITE IN PATIENTS UNDERGOING LOWER LIMB SPLIT THICKNESS SKIN GRAFTING

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ABSTRACT **Introduction:** Pain at split thickness skin graft(SSG) donor site is the most disturbing complication in the early postoperative period. This study evaluated effectiveness of ropivacaine-moistened dressing at donor site in patients requiring SSG. **Methodology:** In this prospective randomised double blind controlled study, 100 patients requiring SSG were divided into two groups N and R of 50 each. Donor site dressing was kept moist with 12 ml/100 cm2 volume of normal saline and 0.2% Ropivacaine in group N and R respectively. The primary outcome measured was amount of rescue analgesic required. The secondary outcomes measured were difference in pain score(VAS), time of administration of 1st and 2nd dose of rescue analgesic and number of patients requiring rescue analgesia in both groups. Categorical data were presented as number (proportion) and continuous variables were presented as Mean±SD. Chi square test and t-test were applied were deemed appropriate. $p<0.05$ was considered as statistically significant **Results:** Total dose of rescue analgesic required was significantly higher in Group N(122.80±73.19 mg v/s 22.76±52.53, p=0.000). Pain scores in group R were significantly low as compared to group N at the 2nd and 6th hours postoperatively [0.98 ± 0.82 v/s 2.28 ±0.88, 1.10 ± 0.91 v/s 1.50 ± 0.86($p<0.05$)]. The time of 1st dose of rescue analgesia was significantly delayed in group R. 90% patients of Group N required rescue analgesic as compared to only 18% in Group R(p=0.0001). **Conclusion:** Ropivacaine moistened dressing is effective in pain relief and reduces rescue analgesic requirement without any untoward side effect in early postoperative period at split thickness skin graft donor site.

KEYWORDS : Thick Skin Split grafting, Moistened dressing, Ropivacaine, Normal saline

INTRODUCTION

Split thickness skin grafting (SSG) are used in burns, reconstructive procedures and extensive wound management for soft tissue defects[1]. The posterolateral part of thigh is most commonly used as a donor site of split thickness skin graft[2].

Pain at split thickness skin graft donor site is probably the most disturbing complication in the first five postoperative days[3]. Alleviation of this pain can achieve considerable reduction in postoperative morbidity and fast recovery[4]. Different methods of reducing pain include application of ice in the donor site, Fascia Iliaca compartment block and different type of dressings[5].

Ropivacaine is a newer long acting aminoamide local anaesthetic agent producing its effects via reversible inhibition of sodium ion influx in nerve fibres. Due to its reduced lipophilicity, ropivacaine has a greater margin of safety with decreased potential for neurotoxicity and cardiotoxicity. Hence ropivacaine soaked dressing is an effective applicable option for split thickness skin graft donor site for early postoperative analgesia[6].

The aim of this study was to compare the effectiveness of ropivacaine moistened dressing and conventional normal saline soaked dressing in patients requiring split thickness skin grafting for reconstruction of various defects.

MATERIALS AND METHODS

After obtaining institutional ethical committee approval (RNT/STAT/IEC/2018/1833) and CTRI registration (CTRI/ 2019/ 03/ 018079), this prospective double blind randomized placebo controlled study was conducted in Department of Anaesthesia, M.B. Government Hospital, attached to RNT Medical College, Udaipur (Raj).

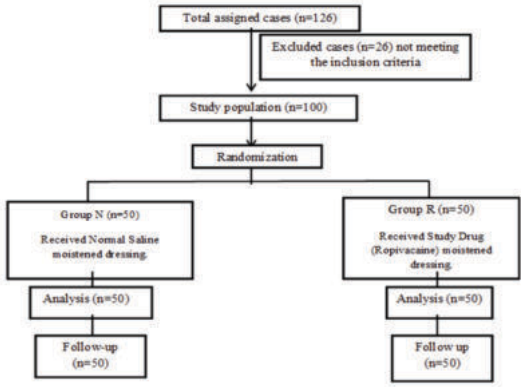
After obtaining written informed consent, the study was conducted on ASA grade I & II patients of either sex, aged 16 to 60 years, who underwent elective split thickness skin grafting for reconstruction of various defects of lower limb under spinal anaesthesia, in whom only thigh was used as donor site for SSG.

Patients with age <16 and >60 years, ASA grade III & IV, bleeding disorder, history of allergy to any component of the dressings, local infection, pregnant women, immunocompromised patients and psychiatric patients were excluded from the study.

A previous study by Raza et al[7] reported a reduction of 93.3% in requirement of rescue analgesia with use of bupivacaine moistened dressing in reduction of postoperative pain at SSG donor site. We postulated that a reduction of rescue analgesia requirement of 60% would be clinically significant. Based on Altmans Nomogram, for the study to have a power of 80% with a $p<0.05$, a total of 45 patients in each group are required. To compensate for dropouts, we recruited 50 patients in each group.

Using computer generated randomization numbers in opaque sealed envelopes, 100 patients were randomly divided into 2 groups of 50 patients each - Group N and group R in which the donor site dressing was kept soaked by instilling normal saline and 0.2% ropivacaine through the catheter placed in dressing gauzes as depicted in consort diagram (Fig 1). For every 100 cm^2 of the donor site wound, 12 ml of the normal saline was instilled once immediately after the surgery and then after 12 hours of the first instillation.

Fig 1 :- CONSORT FLOW CHART



To ensure blinding, drugs were prepared by one anesthesiologist who was not involved further in the study. Another anesthesiologist who conducted the study, instilled the drug and recorded data in the proforma, was unaware of group allocation. Patient and surgeon were

also unaware of group allocation. All patients were kept fasted overnight before surgery. When patients arrived to operation room standard monitoring (pulse oximeter, noninvasive blood pressure, and electrocardiogram) was applied and patient´s baseline vitals [heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and peripheral oxygen saturation (SpO_2)] were noted.

A peripheral intravenous line with 18G cannula was secured, infusion of Ringer lactate was started at rate of 8 ml/min. Patients were administered subarachnoid block in L_3-L_4 space in sitting position with 2.5 ml of hyperbaric 0.5% bupivacaine under all aseptic precautions. After confirming successful block with pin prick method and Bromage scoring, the surgical procedure was started. In all patients skin graft was harvested from the proximal anteromedial and posterolateral aspect of the thigh. The graft was harvested with a Humby's knife/dermatome to produce a homogenous thickness of 0.4 mm. After harvesting the graft, donor site wound was first covered with paraffin tulle then an epidural catheter with multiple holes was placed on this layer of tulle, which was in turn covered with 3 to 4 layer of sterilized gauges and finally covered with a sterilized bandage.

In both groups, the saline/ study drug was instilled through catheter and this was considered as zero time. At the time of drug instillation, the donor site was in horizontal position (on top) so the drug was evenly distributed. Pain was assessed by Visual Analogue Scale (VAS) at an interval of 1,2,6,12,24 hours after end of surgery. Patients who complained of intense pain or in whom VAS score was ≥4 were given rescue analgesics in the form of intravenous tramadol 2 mg/kg.

The amount of study drug/ saline instilled, time of administration of first and subsequent rescue analgesics, cumulative dose and number of doses of rescue analgesics and number of patients requiring rescue analgesics were noted. Vitals were recorded at an interval of 0,1,2,6,12,24 hours. All the patients were followed for any untoward effects like local infection, delayed wound healing during period of hospitalization.

Data were entered into MS EXCEL and analyzed using SPSS version 20. Categorical (qualitative) data were presented as number (proportion) and compared using chi-square test. Continuous variables (quantitative) were presented as Mean±SD and compared using t-test. $p < 0.05$ was considered as statistically significant. The primary outcome measured was amount of rescue analgesic required in 24 hours. The secondary outcomes measured were difference in pain score, number of doses of rescue analgesic doses, time of administration of doses of rescue analgesic and number of patients requiring rescue analgesia in both the groups.

RESULTS

In the present study, control group N and study group R were statistically comparable regarding distribution of age, weight, gender, duration of surgery and volume of drug or normal saline infused (Table 1).

Table 1 : Demographic characteristics of study population

Age (in years)	Group N (n=50)	Group R (n=50)	p value
16-30	30 (60.0%)	30 (60.0%)	0.951
31-45	10 (20.0%)	9 (18.0%)	
>45	10 (20.0%)	11 (22.0%)	
Mean±SD	33.64±14.98	33.98±15.41	0.911
Weight (kg)	52.44±8.832	52.80±11.008	0.857
Gender			
Male	39 (78.0%)	37 (74.0%)	0.640
Female	11 (22.0%)	13 (26.0%)	
ASA Grade			
I	42 (84.0%)	42 (84.0%)	1.000
II	8 (16.0%)	8 (16.0%)	
Duration of surgery (min)	44.9±3.71	44.8±4.04	0.4522
Total volume of drug/NS instilled (ml)			
At 0 hrs	12.60±4.11	11.82±3.96	0.336
At 12 hrs	12.60±4.11	11.82±3.96	0.336
Total dose	25.20±8.22	23.64±7.92	0.336

Pain intensity measured using VAS score was lower in ropivacaine group compared to control group at 2 hours (0.98± 0.82 v/s 2.28± 0.88, p=0.000) and 6 hours (1.10± 0.91 v/s 1.50± 0.86, p=0.026) postoperatively (Table 2).

Table 2. VAS score in two groups

Time interval (hrs)	Group N (n=50)	Group R (n=50)	p value
1	0	0	--
2	2.28±0.88	0.98±0.82	0.000
6	1.50±0.86	1.10±0.91	0.026
12	0.84±0.84	0.94±0.96	0.580
24	0.36±0.48	0.34±0.59	0.854

Mean duration of analgesia (measured upto administration of first dose of rescue analgesia) was prolonged in group receiving ropivacaine moistened dressing (235.00±54.95 min) as compared to control group (188.0 ±29.64 min). However, time of administrating 2nd dose of rescue analgesia was similar in both the groups(Table 3). The number of patients receiving rescue analgesia, total amount and number of doses of rescue analgesic administered was very less in patients receiving ropivacaine moistened dressing(Table 3).

Table 3. Rescue analgesia characteristics

No. of dose	Group N (n=50)	Group R (n=50)	p value
Time of rescue analgesia 1st dose (min)(Mean±S.D)	188.00±29.64	235.00±54.95	0.0001
Time of rescue analgesia 2nd dose (min)(Mean±S.D)	561.50±84.18	572.50±38.89	0.862
No. of patients receiving rescue analgesia	45 (90.00%)	9 (18.00%)	0.0001
No. of doses received	57	12	0.001
Total dose (mg) of rescue analgesia	122.80±73.19	22.76±52.53	0.000

Patients in both the groups had comparable haemodynamics (SBP, DBP, HR) throughout the 24 hours postoperatively (Fig 2).

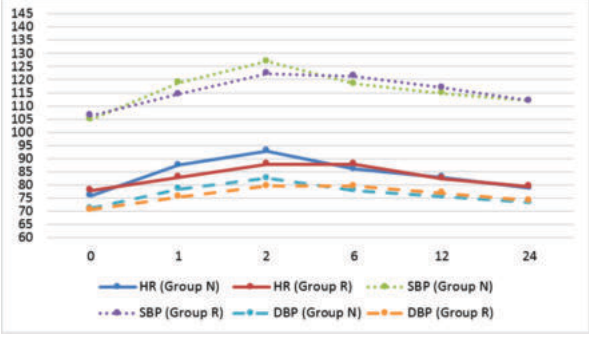


Fig 2 :- Haemodynamic parameters of study population

DISCUSSION

Local anaesthetic drugs have become increasingly popular in the treatment of surgical pain due to analgesic properties and lack of opioid induced adverse effects.[8] Continuous wound infiltration of local anaesthetics has emerged as one of the important analgesic techniques both as a standalone technique and as an adjunct to multimodal analgesia.[8,9] Placement of a catheter at the surgical site enables the administration of intermittent boluses[10] or continuous infusion[11] of local anaesthetic for a prolonged effect.

We planned this study to evaluate the effectiveness of ropivacaine soaked dressing at donor site in management of postoperative pain in patients undergoing lower limb SSG.

It has been universally accepted that moist dressing at split thickness skin grafting donor site has better results over dry dressing both in terms of healing and pain management. In the present study moist dressing was used in both groups to ensure that the analgesic effect was due to local anaesthetic effect and not due to moist nature of dressing[7]. In the present study, postoperative pain score as assessed by VAS at 1st hour of postoperative period was 0 in both the groups. This can be

explained by the fact that the patients were still under the sensory block of spinal anaesthesia. To ensure that adequate effect of ropivacaine was achieved before the effect of subarachnoid block weans off, the drug was instilled at donor site while the patient was still under the effect of spinal anaesthesia.

In our study, pain scores were low in patients receiving ropivacaine moistened dressings at the 2nd and 6th hr postoperatively. The results of our study find support in study by Muhammad Sheraz Raza et al[7] who observed that patients with bupivacaine 0.25% moistened dressing at SSG donor site had lower VAS as compared with patient receiving normal saline moistened dressing. Similarly, Jenwitheesuk K et al[3] also noted a higher pain relief score defined as the difference between pain score before and after dressing in Bupivacaine group during the first five postoperative days compared to control group B in patients undergoing SSG of lower limb.

In the present study, the time of administration of first dose of rescue analgesia was delayed in patients receiving ropivacaine moistened dressing. Similar to our study, Jenwitheesuk K et al[3] noted in their study that during the first five postoperative days, the pain relief duration was prolonged with bupivacaine moistened dressing at donor site.

Local anaesthetic primarily act by inhibiting the nociceptive transmission from the surgical wound by blocking the voltage-gated sodium channels expressed on small-diameter neurons[12]. It is possible that local anaesthetics may also have anti-inflammatory properties which may contribute to the analgesic effect[13]. Local anaesthetics may also produce analgesia by absorption into the systemic circulation. It has been shown that even low doses of intravenous local anaesthetic reduce the development of central hyperalgesia[14]. Local anaesthetic wound instillation decreases injury induced C fiber activity with consequent attenuation of peripheral and central sensitivity[15].

In our study, only 9(18%) patients of ropivacaine group demanded rescue analgesic doses compared to 45(95%) patients in control group. Our findings are supported by a study on evaluating the effectiveness of bupivacaine moistened dressing on SSG donor site by Raza et al,[7] in which only 5 out of 75 (6.67%) patients required rescue analgesic doses compared to 72 out of 75 (96%) patients in control group. Jenwitheesuk K et al[3] in their study on use of bupivacaine moistened dressing at SSG donor site also noted a fewer number of patients in Bupivacaine group requiring intravenous pethidine as rescue analgesic for pain relief postoperatively as compared to control group(6 v/s 16 on day 1st, 4 v/s 13 on day 2nd).

In the present study the total number of doses of intravenous tramadol as rescue analgesic received by patients in ropivacaine group were significantly less. Our result are supported by a study done by Chester JF et al,[16] in which they observed that on 1st and 2nd postoperative day patients perfused with saline demanded more than 3 and 5 times respectively, the number of doses of intravenous pethidine as rescue analgesics through PCAD (Patient Controlled Analgesic Device), compared with those receiving bupivacaine for wound perfusion following elective cholecystectomy. Also the actual number of doses of pethidine delivered to patients were lower in patients receiving bupivacaine compared to those receiving normal saline (9 v/s 18 on day 1st, 6 v/s 17 on day 2nd).

In the present study, the total dose of intravenous tramadol as rescue analgesic received by patients in ropivacaine group R was significantly lesser compared to control group. Zohar E et al[17] in their study noted that during the first 6 hour after the operation, the total rescue morphine administered was 6 ± 4 mg vs 12 ± 6 mg ($p < 0.001$) for the Bupivacaine and Control groups, respectively. The total rescue meperidine administered during the next 18 h after surgery was 29 ± 37 mg vs 95 ± 36 mg ($p < 0.001$) for the Bupivacaine and Control groups, respectively. Their findings supports our results. In another study by Fredman et al[18], they noted that the total rescue morphine administered through patient controlled elastometric pump during the first 6 postoperative hours was 2±3 mg v/s 10± 5 mg ($p<0.01$) for the ropivacaine and control group respectively in patients undergoing cesarean section.

Local anaesthetic wound instillation has been shown to be associated with catheter related infection, delayed wound healing and local anaesthetic induced myotoxicity. However, in present study we did not observed any unwanted side effects. In clinical setting, local anaesthetic induced myotoxicity seems to be rare because local anesthetic-induced analgesia and anesthesia is achieved at a dosage insufficient to produce clinically recognizable myotoxicity[17]. In our study, myotoxicity was not specifically assessed. However, considering our study design, this complication is unlikely because the local anesthetic was not injected directly into muscle or subcutaneous tissue.

Some authors[19] postulate that wound infiltration with local anesthetic may interfere with wound closure and normal wound healing. This hypothesis seems to be more important in damaged and infected tissues in which the inflammatory cascade is crucial to wound healing. Conversely, it is possible that partial blockade of the inflammatory response in the first phase of wound closure may be beneficial and may result in less fibroblast hyperplasia and therefore a decreased risk of hypertrophic scar formation. Our results showed no difference between groups regarding wound healing and risk of infection. However, a larger number of patients would be needed to study this issue further.

Limitations

The concentration of ropivacaine in plasma was not assessed in present study. This holds significance specially when higher doses of ropivacaine are used. The plasma unbound ropivacaine level should be below toxic threshold (600 ng/ml). Analgesic effect was assessed for a period of 24 hours only. However this study aimed at evaluating the analgesic efficacy of Ropivacaine in wound instillation during immediate post operative period only. The optimal concentration and amount of ropivacaine needed for postoperative pain relief was not determined in our study. Further studies using different concentration and volume of ropivacaine are needed.

CONCLUSION

We conclude that 0.2% Ropivacaine moistened dressing after split thickness skin grafting at donor site provides better postoperative pain relief, reduces rescue analgesic requirement without any untoward side effects.

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