European Journal of Obstetrics & Gynecology and Reproductive Biology 236 (2019) 154–159

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Full length article

Intraoperative local infiltration with ropivacaine 0.5% in women undergoing vaginal hysterectomy and pelvic floor repair: Randomized double-blind placebo-controlled trial

Stavros Athanasiou[a,*], Sophia Hadzillia[b], Eleni Pitsouni[a], Stamatios Kastanias[a], Athanasios Douskos[c], Dimitris Valsamidis[b], Dimitris Loutradis[c], Themos Grigoriadis[a]

[a] Urogynaecology Unit, 1st Department of Obstetrics and Gynaecology, 'Alexandra' Hospital, National and Kapodistrian University of Athens, Athens, Greece
[b] Department of Anaesthesiology, 'Alexandra' Hospital, Athens, Greece
[c] 1st Department of Obstetrics and Gynaecology, 'Alexandra' Hospital, National and Kapodistrian University of Athens, Athens, Greece

ARTICLE INFO

Article history:
Received 12 October 2018
Received in revised form 12 December 2018
Accepted 12 March 2019

Keywords:
Hysterectomy
Anterior colporrhaphy
Posterior colporrhaphy
POP
McCall culdoplasty
Pain

ABSTRACT

Objective: To evaluate the effectiveness of infiltration with ropivacaine 0.5% on controlling postoperative pain in women undergoing vaginal hysterectomy (VH) and pelvic floor repair for prolapse stage > II.
Study design: This double-blind randomized 1:1 placebo-controlled trial included 59 women. Thirty millilitres of ropivacaine 0.5% or placebo was infiltrated in the round and uterosacral ligaments and in the perineal body. Primary outcomes included postoperative pain intensity at rest and during cough (measured using 10-cm visual analogue scale), and proportion of patients reporting moderate/severe pain. Secondary outcomes included morphine consumption and assessment of nausea, vomiting and sedation. Outcomes were compared between groups at 2, 4, 8 and 24 h postoperatively. Statistical (*p*-values) and clinical significance {effect size [Cliff's delta] [95% confidence interval (CI)] and odds ratio (95% CI)} of results were assessed. Outcomes are presented as median (min–max) and *n* (%).
Results: Pain intensity was lower after ropivacaine infiltration compared with placebo at 2 and 4 h postoperatively at rest [0.5 (0.1–7.2) vs 1.1 (0.2–9.3) ($p = 0.007$) and 1.3 (0.1–5.1) vs 3.1 (0.1–9.8) ($p = 0.02$), respectively] and during cough [0.9 (0.1–8.9) vs 1.9 (0.1–10) ($p = 0.03$) and 1.6 (0.1–4.7) vs 3.2 (0.3–9.6) ($p = 0.009$), respectively]. The proportion of patients with moderate/severe pain was significantly less after ropivacaine infiltration compared with placebo at 2, 4 and 8 h postoperatively at rest [4% vs 32% ($p = 0.03$), 16% vs 44% ($p = 0.03$) and 12% vs 40% ($p = 0.02$), respectively] and during cough [8% vs 40% ($p = 0.008$), 16% vs 52% ($p = 0.007$) and 20% vs 52% ($p = 0.02$), respectively]. Patients in the ropivacaine group consumed significantly less morphine compared with those in the placebo group up to 24 h postoperatively [4 (0–17) mg vs 7 (0–19) mg ($p = 0.02$)]. The incidence of nausea and vomiting was 3 (12%) and 0–2 (0–8%) in the ropivacaine group, compared with 1–7 (4–28%) and 1–4 (4–16%) in the placebo group. No significant difference was found in the proportion of patients using morphine, proportion of patients reporting the presence of nausea/vomiting, and the intensity of sedation between the groups (all $p > 0.05$).
Conclusion: Local infiltration with ropivacaine 0.5% significantly reduces postoperative pain and morphine consumption in patients undergoing VH and pelvic floor repair for advanced pelvic organ prolapse.

Introduction

Pelvic organ prolapse (POP) is a common condition that may present in up to 53% of women, with 14–19% of them undergoing pelvic reconstructive surgery up to the age of 80 years [1–4]. Vaginal surgery is most commonly preferred as it carries less morbidity compared with abdominal approaches, and can be performed under regional anaesthesia [3–8]. Despite the relative low morbidity associated with vaginal procedures, postoperative pain management remains an important issue.

Pain is defined as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage' [9]. Adequately controlled postoperative pain correlates with better quality of care, reducing patient discomfort and dissatisfaction, time to mobilization and morbidity [10]. The goal of postoperative pain management is pain

* Corresponding author at: Urogynaecology Unit, 1st Department of Obstetrics and Gynaecology, 'Alexandra' Hospital, Medical School, National and Kapodistrian University of Athens, Vasilisis Sofias Ave. 80, 11528, Athens, Greece.
E-mail address: stavros.athanasiou@gmail.com (S. Athanasiou).

https://doi.org/10.1016/j.ejogrb.2019.03.016
0301-2115/

relief with the minimum of adverse events [11,12]. In vaginal surgery, postoperative pain control is performed following a multimodal approach which includes opioids and non-steroidal anti-inflammatory drugs (NSAIDs) [13]. Opioids modulate the effect of nocireceptors in the central nervous system and peripheral tissues, while NSAIDs block prostaglandin production mediating an anti-inflammatory response [11,12]. Both opioids and NSAIDs have side effects (i.e. nausea, vomiting, sedation, etc.) that may prolong time to first mobilization and duration of hospital stay [11,12]. Additionally, some of their side effects can be serious (i.e. respiratory depression, hypoxia and respiratory arrest, platelet dysfunction and bleeding, altered liver function, etc.), especially in certain groups of patients such as elderly, obese or chronic pain patients [11,12].

Local infiltration with anaesthetics blocks peripheral sensory nerves with low or absent systematic side effects [12]. Hence, the addition of local infiltration with ropivacaine 0.5% has been used in surgery to augment the efficacy of pain control, minimizing the side effects of opioids and NSAIDs [11,12,14]. In obstetrics and gynaecology, ropivacaine 0.5% has been used for reducing postoperative pain following caesarean section or vaginal labour, as well as vaginal hysterectomy (VH) for benign conditions (i.e. gynaecological bleeding, dysplasia, uterine fibroids and pain) [15–19]. Nevertheless, it remains unknown whether patients undergoing VH and pelvic floor repair for POP under combined spinal-epidural block (CSE) may benefit from local infiltration with ropivacaine 0.5%.

The aim of this study was to evaluate the effect of intraoperative local infiltration with ropivacaine 0.5% on postoperative pain in patients with symptomatic POP stage > II undergoing VH and pelvic floor repair. Specifically, women receiving local ropivacaine infiltration in the round ligaments (RL), the uterosacral ligaments (USL) and the perineal body (PB) were compared with women receiving placebo infiltration at the same sites.

Methods

This randomized 1:1 placebo-controlled double-blind study was performed in a urogynaecological unit at a tertiary hospital in accordance with the Declaration of Helsinki, and approved by the local ethics committee. The recruitment process included medical history, gynaecological examination, and anaesthesiologist evaluation using the American Society of Anesthesiologists (ASA) physical status classification system [20]. All participants signed appropriate informed consent forms.

Women undergoing VH and pelvic floor repair due to POP stage > II, aged 45–80 years, were considered eligible for recruitment.

Women with a history of chronic systemic disease (i.e. autoimmune diseases), chronic pain disorder, gynaecological cancer, neurological or psychological disorder, alcoholism or drug abuse, allergy to any drug used in the protocol, renal or hepatic failure, insulin-dependent diabetes mellitus, ASA class ≥ III, preoperative administration of opioids, or contraindications to epidural anaesthesia were excluded from enrolment in this study.

After recruitment, women were excluded from the study if the duration of surgery was <1 h and >3 h, any type of anaesthesiologic complication occurred (e.g. admission to intensive care unit), general anaesthesia was needed due to epidural failure, or an additional dose of local anaesthetic was administered from the epidural catheter.

Description of intervention

CSE block was performed by the loss of resistance technique, and 2.5 ml ropivacaine 0.75% plus 15 μg fentanyl were administered in the subarachnoid space in all participants. Additionally, at the beginning of surgery, all women received antibiotics (o.d. i.v.), metoclopramide 10 mg, ranitidine 100 mg, diclofenac 75 mg and paracetamol 1 g.

Eligible participants were allocated at random to the ropivacaine group or the placebo group by an independent anaesthesiologist (HS) who was not involved in any other part of the study. The ropivacaine group received an infiltration of 30 ml ropivacaine 0.5% [5 ml in RL and 5 ml in USL (bilaterally), and 10 ml in PB], while the placebo group received an infiltration of 30 ml placebo solution (N/S 0.9%) [5 ml in RL and 5 ml in USL (bilaterally), and 10 ml in PB]. To minimize the risk of intravascular injection, a negative aspiration was always performed. An independent anaesthesiologist (DV) who was not involved in the evaluation process prepared the infiltrating solutions, which had an identical appearance. The participants and gynaecologists performing VH and pelvic floor repair (McCall culdoplasty, anterior and posterior colporrhaphy, and perineoplasty) (AS and TG) were blinded to the group allocation.

A patient-controlled analgesia (PCA) pump was placed in all participants, containing 40 mg morphine (0.5 mg/ml) plus 8 mg ondansetron (0.1 mg/ml). PCA was started after the end of surgery with a demand dose of morphine 1 mg i.v., a lockout period of 7 min after each bolus, and a maximum allowed dose of 16 mg/2 h. In addition, all participants received metoclopramide 10 mg/12 h i.v., ranitidine 100 mg/12 h i.v., paracetamol 1 g/8 h i.v. and diclofenac suppository 75 mg/12 h. Additionally, ondasetron 4 mg i.v. was used to treat nausea and vomiting whenever necessary.

The primary outcomes included pain intensity [measured by 10-cm visual analogue scale (10-cm VAS)] [21,22] and the number of patients with moderate/severe pain (pain ≥4 on 10-cm VAS). The evaluation of pain included assessment of static pain when the patients were at rest, and assessment of dynamic pain after asking patients to produce a forceful cough.

The secondary outcomes included cumulative morphine consumption (in mg), number of patients who used PCA, number of patients who reported the presence of nausea or vomiting (incidence of nausea or vomiting), and the level of sedation (measured by 10-cm VAS).

All outcomes (primary and secondary) were collected and/or evaluated at 2, 4, 8 and 24 h postoperatively by three independent gynaecologists (EP, SK and AD) who were blinded to the group allocation.

Statistical analyses

Sample size was calculated based on a previous study [18]. For a power of 80% and level of statistical significance of 5%, 42 participants (21 in each arm) were required for reduction of pain intensity. After allowing for a 40% non-response/drop-out rate and considering those who did not receive the allocated intervention (i.e. prolonged operating time due to surgical complications), 59 participants were required.

The randomization process was performed with a 1:1 ratio and blocking restriction by an independent statistician using the Sealed Envelope website (https://www.sealedenvelope.com/simple-randomiser/v1/lists). Allocation concealment was performed using sealed opaque envelopes containing sequential numbers. The sealed opaque envelopes were retained in a safe locked place and were accessible only by an independent nurse.

The Shapiro–Wilk test and normality plots were used to assess the distribution of continuous outcomes. Normally distributed data were analysed using Student's *t*-test for independent samples. Non-normally distributed data were analysed using the Mann–

Whitney *U*-test. Categorical data were analysed using the Chi-squared test when expected counts were ≥5 in >20% of cells, while Yates' correction and Fisher's exact test were used when expected counts were <5 in >20% of cells (highest *p*-values were selected). Cliff's delta [95% confidence interval (95% CI)] [23,24] and odds ratio (95% CI) were used to measure the effect size for skewed and categorical data, respectively. Small, moderate and large effects were defined as Cliff's delta values of 0.147, 0.33 and 0.474, respectively [24]. Data are presented as median (minimum–maximum) and *n* (%). Statistical significance was set at 5% ($p < 0.05$). Effect size was defined using https://effect-size-calculator.herokuapp.com/ and VBA/Excel (Microsoft Corp., Redmond, WA, USA) [25]. All other analyses were performed using SPSS Version 25.0 (ICM Corp., Armonk, NY, USA).

Results

The allocation process of the study population is presented in Fig. 1. Overall, 82 patients were screened. Fifty-nine patients (29 and 30 in the ropivacaine and placebo groups, respectively) undergoing surgery were recruited, of which 50 (25 in each arm) were finally included in the study. Characteristics of the groups are presented in Table 1. There were no differences in age, height, weight, body mass index and duration of surgery between the groups.

Median pain intensity at rest and during cough were significantly lower in the ropivacaine group compared with the placebo group up to 4 h postoperatively (Table 2). The effect of ropivacaine in reducing postoperative pain (at rest and during

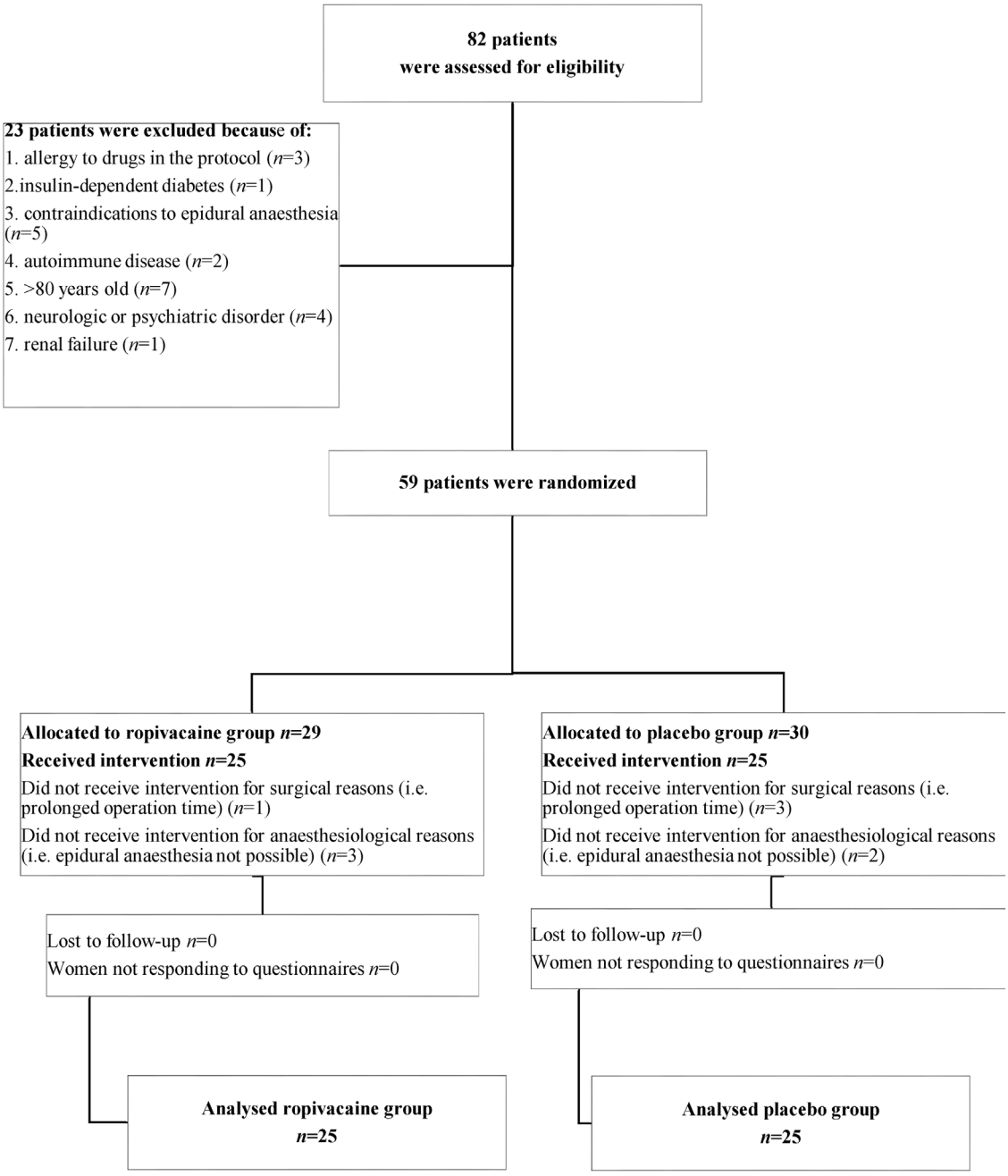

Fig. 1. Study flowchart.

Table 1
Characteristics of the ropivacaine and placebo groups.

	Ropivacaine group ($n = 25$)[a]	Placebo group ($n = 25$)[a]	p-value[a]
Age	66 (53–80)	70 (47–80)	0.2
Height (cm)	164 (150–174)	160 (147–168)	0.5
Weight (kg)	68 (51–90)	66 (50–101)	0.1
Body mass index	26.1 (18.4–36.1)	25.8 (17.7–40.1)	0.4
Operation time (min)	137.5 (98–180)	140 (103–180)	0.8

[a] Data are presented as median (minimum–maximum). Comparison of age was performed by independent-samples t-test. Comparison of body mass index and operation time was performed by Mann–Whitney U-test. Statistical significance was set at 5% ($p < 0.05$).

Table 2
Primary outcomes at 2 h, 4 h, 8 h and 24 h postoperatively.

	Ropivacaine group ($n = 25$)[b]	Placebo group ($n = 25$)[b]	Effect size[b]	p-value[b]
Pain at rest[a]				
2 h				
Median (min–max)	0.5 (0.1–7.2)	1.1 (0.2–9.3)	−0.44 (95% CI −0.12 to −0.68)	**0.007**
Moderate/severe intensity	1 (4%)	8 (32%)	OR 0.1 (95% CI 0.004–0.65)	**0.03**
4 h				
Median (min–max)	1.3 (0.1–5.1)	3.1 (0.1–9.8)	−0.37 (95% CI −0.05 to −0.63)	**0.02**
Moderate/severe intensity	4 (16%)	11 (44%)	OR 0.24 (95% CI 0.05–0.87)	**0.03**
8 h				
Median (min–max)	1.3 (0.2–8.4)	2.6 (0.1–9.1)	−0.3 (95% CI 0.03 to −0.57)	0.08
Moderate/severe intensity	3 (12%)	10 (40%)	OR 0.2 (95% CI 0.05–0.87)	**0.02**
24 h				
Median (min–max)	0.5 (0–7)	0.6 (0–5.5)	−0.03 (95% CI 0.3 to −0.34)	0.9
Moderate/severe intensity	2 (8%)	1 (4%)	OR 2 (95% CI 0.18–24.6)	1
Pain during cough				
2 h				
Median (min–max)	0.9 (0.1–8.9)	1.9 (0.1–10)	−0.36 (95% CI −0.03 to −0.62)	**0.03**
Moderate/severe intensity	2 (8%)	10 (40%)	OR 0.13 (95% CI 0.03–0.68)	**0.008**
4 h				
Median (min–max)	1.6 (0.1–4.7)	3.2 (0.3–9.6)	−0.4 (95% CI −0.11 to −0.67)	**0.009**
Moderate/severe intensity	4 (16%)	13 (52%)	OR 0.18 (95% CI 0.05–0.66)	**0.007**
8 h				
Median (min–max)	1.7 (0.2–8.5)	4 (0.1–9.5)	−0.31 (95% CI 0.02 to −0.58)	0.06
Moderate/severe intensity	5 (20%)	13 (52%)	OR 0.23 (95% CI 0.07–0.8)	**0.02**
24 h				
Median (min–max)	0.5 (0.1–5.8)	1 (0–6.4)	−0.13 (95% CI 0.2 to −0.43)	0.4
Moderate/severe intensity	3 (12%)	1 (4%)	OR 3.27 (95% CI 0.32–33.84)	0.6

CI, confidence interval; OR, odds ratio.
[a] Moderate/severe pain is defined as values ≥4 in 10-cm visual analogue scale.
[b] Outcomes are presented as median (minimum–maximum) and n (%). Comparisons of continuous outcomes were performed using Mann–Whitney U-test. Comparisons of categorical outcomes were performed using Chi-squared test when expected counts were ≥5 in >20% of cells. In cases where expected counts were <5 in >20% of cells, Yates' correction of Chi-squared test and Fisher's exact test were used, and the highest p-value is presented. Cliff's delta (95% CI) and OR (95% CI) are presented for effect size of continuous and categorical data, respectively. Statistical significance was set at 5% ($p < 0.05$). Numbers in bold indicate statistically significant results.

cough) was clinically meaningful up to 4 h (Cliff's delta 0.36–0.44) (Table 2). The number of women reporting moderate/severe pain was significantly lower in the ropivacaine group compared with the placebo group at rest and during cough up to 8 h postoperatively (Table 2, Figs. 2 and 3). The odds of having moderate/severe pain in the ropivacaine group was 76–90% less than in the placebo group up to 8 h postoperatively (Table 2).

Participants in the ropivacaine group consumed (cumulatively) significantly less morphine at 4, 8 and 24 h postoperatively compared with the placebo group (Table 3). The effect of ropivacaine in reducing morphine consumption 4–24 h postoperatively was clinically meaningful (Cliff's delta 0.34–0.4) (Table 3). The number of participants using morphine at each time point did not differ between the groups (Table 3). The odds of morphine administration in the ropivacaine group at 4–24 h was 24–62% less than in the placebo group (Table 3). The presence of nausea and/or vomiting and/or sedation did not differ between the groups (Table 3). The odds of having nausea and/or vomiting (2–8 h postoperatively) was 28–78% less in the ropivacaine group compared with the placebo group (Table 3).

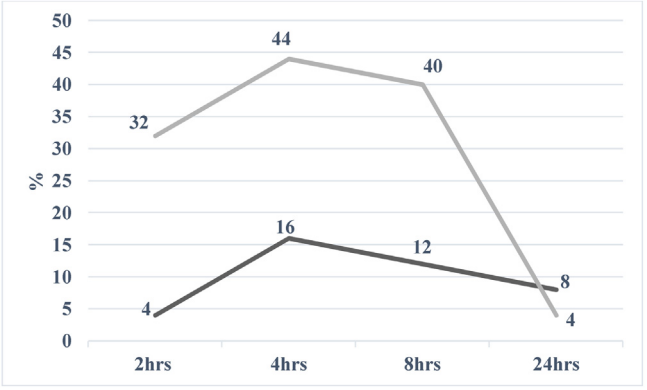

Fig. 2. Percentage of patients with moderate/severe pain at rest. A significant difference was found in favour of the ropivacaine group at 2, 4 and 8 h postoperatively ($p = 0.03$, 0.03 and 0.02, respectively). Black line, ropivacaine group; grey line, placebo group.

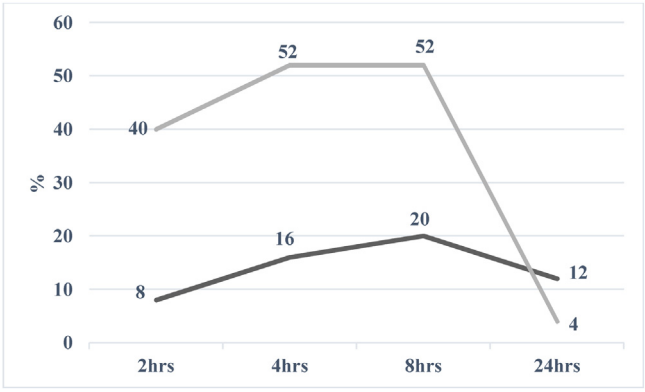

Fig. 3. Percentage of patients with moderate/severe pain during cough. A significant difference was found in favour of the ropivacaine group at 2, 4 and 8 h postoperatively ($p = 0.008$, 0.007 and 0.02, respectively). Black line, ropivacaine group; grey line, placebo group.

None of the patients had any adverse events related to infiltration with ropivacaine 0.5%.

Comment

The findings of this study suggest that patients undergoing VH and pelvic floor repair for POP could benefit from local infiltration with ropivacaine 0.5%. In comparison with placebo, ropivacaine significantly reduced pain intensity and the proportion of patients reporting moderate/severe pain up to 8 h postoperatively. The decrease in postoperative pain was reflected by significantly lower morphine consumption up to 24 h postoperatively. The results of this study were also clinically meaningful as the odds of having moderate/severe pain postoperatively, needing to use morphine and experiencing nausea/vomiting were 76–90%, 24–62% and 28–78% less after ropivacaine infiltration, respectively. Nevertheless, the adverse events of morphine consumption (i.e. nausea, vomiting and sedation) did not differ significantly between patients who received ropivacaine and those who received placebo.

Ropivacaine's duration of local sensory block ranges from approximately 6–10 h [19,26,27]. Specifically, Hirstovska et al., who evaluated local ropivacaine infiltration in women undergoing VH for benign conditions, found that postoperative pain was reduced for up to 8 h [19]. In the present study, pain intensity was reduced up to 4 h postoperatively, which is shorter than the results of previous studies. It is hypothesized that pain relief following ropivacaine infiltration might be explained by the blocking of sensory nerves in the RL, the USL and the PB. Thus, the difference in sensory duration between the present results and those reported previously might be explained by the time interval between infiltration and the end of surgery, resulting in a difference of approximately 1.5 h between RL and PB infiltration. Furthermore, this study included women up to 80 years of age, which is a representative population of women with symptomatic POP. It has been found that women aged <60 years are more likely to report higher levels of pain after pelvic reconstruction compared with women aged >60 years [28]. Thus, the inclusion of older women in the present study may have led to an underestimation of the effectiveness of ropivacaine for reducing postoperative pain.

The proportion of patients who reported moderate/severe pain was significantly lower after ropivacaine infiltration compared

Table 3
Secondary outcomes at 2, 4, 8 and 24 h postoperatively.

	Ropivacaine group ($n = 25$)[a]	Placebo group ($n = 25$)[a]	Effect size[a]	p-value[a]
Morphine administration				
2 h				
Median (min–max) (mg)	1 (0–7)	2 (0–6)	−0.11 (95% CI 0.2 to −0.41)	0.4
Patients using morphine	20 (80%)	19 (76%)	OR 1.26 (95% CI 0.33–4.83)	0.7
4 h				
Median (min–max) (mg)	3 (0–16)	6 (0–18)	−0.34 (95% CI −0.07 to −0.6)	**0.04**
Patients using morphine	15 (60%)	20 (80%)	OR 0.38 (95% CI 0.1–1.33)	0.1
8 h				
Median (min–max) (mg)	4 (0–16)	7 (0–19)	−0.4 (95% CI −0.08 to −0.64)	**0.02**
Patients using morphine	14 (56%)	19 (76%)	OR 0.4 (95% CI 0.12–1.35)	0.1
24 h				
Median (min–max) (mg)	4 (0–17)	7 (0–24)	−0.4 (95% CI −0.08 to −0.65)	**0.02**
Patients using morphine	12 (48%)	14 (56%)	OR 0.76 (95% CI 0.24–2.2)	0.6
Nausea				
2 h	3 (12%)	5 (20%)	OR 0.54 (95% CI 0.12–2.58)	0.7
4 h	3 (12%)	4 (16%)	OR 0.72 (95% CI 0.14–3.59)	1
8 h	3 (12%)	7 (28%)	OR 0.35 (95% CI 0.08–1.55)	0.3
24 h	3 (12%)	1 (4%)	OR 3.27 (95% CI 0.32–33.84)	0.6
Vomiting				
2 h	0 (0%)	1 (4%)	OR 0.46 (95% CI 0.09–9.87)	1
4 h	2 (8%)	4 (16%)	OR 0.46 (95% CI 0.04–3.62)	0.7
8 h	1 (4%)	4 (16%)	OR 0.22 (95% CI 0.02–2.11)	0.3
24 h	2 (8%)	2 (8%)	OR 1 (95% CI 0.13–7.72)	1
Intensity of sedation				
2 h	2 (0–10)	0 (0–9)	0.13 (95% CI 0.4 to −0.18)	0.4
4 h	5 (0–10)	2 (0–9)	0.19 (95% CI 0.48 to −0.13)	0.2
8 h	5 (0–10)	2 (0–10)	0.09 (95% CI 0.39 to −0.23)	0.6
24 h	0 (0–8)	0 (0–7)	0.09 (95% CI 0.34 to −0.19)	0.5

CI, confidence interval; OR, odds ratio.

[a] Outcomes are presented as median (minimum–maximum) and n (%). Comparisons of continuous outcomes were performed using Mann–Whitney U-test. Comparisons of categorical outcomes were performed using Chi-squared test when expected counts were ≥5 in >20% of cells. In cases where expected counts were <5 in >20% of cells, Yates' correction of Chi-squared test and Fisher's exact test were used, and the highest p-value is presented. Cliff's delta (95%) and OR (95% CI) are presented for effect size of continuous and categorical data, respectively. Statistical significance was set at 5% ($p < 0.05$). Numbers in bold indicate statistically significant results.

with placebo up to 8 h postoperatively. This is a significant result as patients with moderate/severe pain are more likely to need opioids to relieve their pain. Indeed, in the present study, the reduction in postoperative pain was accompanied by significantly lower consumption of morphine up to 24 h postoperatively. Furthermore, a 1-cm reduction in acute postoperative pain intensity measured by the 10-cm VAS is considered to be clinically important [22]. The present study found that the median differences in pain between the ropivacaine and placebo groups at rest and during cough reached or even exceeded 1 cm up to 8 h postoperatively.

Diminished pain intensity and morphine consumption after ropivacaine infiltration was not accompanied by a significant lower proportion of patients reporting nausea/vomiting or level of sedation, although a trend in favour of the ropivacaine group was apparent. This is in accordance with the results of a previous study [19]. In the present study, a possible reason why the incidence of nausea and vomiting was not significantly lower in the ropivacaine group could be due to administration of anti-emetics (metoclopramide every 12 h i.v. and ondansetron via the PCA pump) and systematic NSAIDs.

To the authors' knowledge, this is the first study to evaluate local infiltration with ropivacaine 0.5% for controlling postoperative pain in women undergoing VH and pelvic floor repair for advanced POP > stage II under CSE block. In the field of vaginal surgery, only one study has evaluated the effectiveness of local infiltration on postoperative pain. In that study, VH was performed for other benign conditions without pelvic floor repair under general anaesthesia, and participants were much younger (aged 32–67 years) than those included in the present study (aged 47–80 years). However, the inclusion of women aged ≤80 years reflects the real-world population of patients with symptomatic POP.

A possible limitation of this study is the administration of maximum postoperative analgesia (including PCA pump releasing morphine freely on demand by the participants), which may mask the efficacy of local infiltration of ropivacaine. However, the authors could not predict a priori the effect of ropivacaine infiltration, and it would not be ethical to withhold adequate postoperative analgesia from the participants. Another possible limitation of this study is that the study design and small sample size do not enable a sensitivity analysis to be performed for factors such as age, POP stage, body mass index etc. Moreover, ropivacaine 0.5% was used in a prespecified volume. In peripheral block, ropivacaine acts in a dose–response manner [28]. Thus, it remains unknown whether other concentrations and different volumes could act differently in the management of pain after VH and pelvic floor repair.

Conclusions

Local infiltration with ropivacaine 0.5% can reduce postoperative pain and morphine consumption in women undergoing VH and pelvic floor repair for POP. Further well-designed randomized controlled trials are needed to define the optimum volume of ropivacaine, and to identify which women could gain the greatest benefit from this modality of postoperative pain management.

Conflict of interest

None declared.

Funding sources

None.

References

[1] Wu JM, Vaughan CP, Goode PS, Redden DT, Burgio KL, Richter HE, et al. Prevalence and trends of symptomatic pelvic floor disorders in U.S. women. Obstet Gynecol 2014;123:141–8.
[2] Barber MD. Pelvic organ prolapse. BMJ 2016;354:i3853.
[3] Haya N, Feiner B, Baessler K, Christmann-Schmid C, Maher C. Perioperative interventions in pelvic organ prolapse surgery. Cochrane Database Syst Rev 2018;8:CD013105.
[4] Aube M, Tu LM. Current trends and future perspectives in pelvic reconstructive surgery. Womens Health (Lond) 2018;14: 1745506518776498.
[5] Haylen BT, Maher CF, Barber MD, Camargo S, Dandolu V, Digesu A, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female joint report on the terminology for female pelvic organ prolapse (POP). Neurourol Urodyn 2016;35:137–68.
[6] Douskos A, Pitsouni E, Grigoriadis T, Athanasiou S. Surgical management of pelvic organ prolapse: an update. HJOG 2016;16:1–6.
[7] Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2013;4:CD004014.
[8] Cvach K, Dwyer P. Surgical management of pelvic organ prolapse: abdominal and vaginal approaches. World J Urol 2011;30:471–7.
[9] International Association for the Study of Pain. IASP terminology. Washington, DC: IASP; 2018 Available at: http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698#Pain (last accessed 27 September 2018).
[10] Gunningberg L, Idvall E. The quality of postoperative pain management from the perspectives of patients, nurses and patient records. J Nurs Manag 2007;15:756–66.
[11] Ramsay MAE. Acute postoperative pain management. BUMC Proc 2000;13:244–7.
[12] Garimella V, Cellini C. Postoperative pain control. Clin Colon Rectal Surg 2013;26:191–6.
[13] Cllins SA, Joshi G, Quiroz LH, Steinberg AC, Nihira MA. Pain management strategies for urogynecologic surgery: a review. Female Pelvic Med Reconstr Surg 2014;20:310–5.
[14] Simpson D, Curran MP, Oldfield V, Keating GM. Ropivacaine: a review of its use in regional anaesthesia and acute pain management. Drugs 2005;65:2675–717.
[15] Bamigboye AA, Justus HG. Ropivacaine abdominal wound infiltration and peritoneal spraying at cesarean delivery for preemptive analgesia. Int J Gynaecol Obstet 2008;102:160–4.
[16] Schinkel N, Colbus L, Soltner C, Parot-Schinkel E, Naar L, Fournie A, et al. Perineal infiltration with lidocaine 1%, ropivacaine 0.75% or placebo for episiotomy repair in parturients who received epidural labor analgesia: a double-blind randomized study. Int J Obstet Anesth 2010;19:293–7.
[17] Gutton C, Bellefleur JP, Puppo S, Brunet J, Antonini F, Leone M, et al. Lidocaine versus ropivacaine for perineal infiltration post-episiotomy. Int J Gynaecol Obstet 2013;122:33–6.
[18] Larsen KR, Kristensen BB, Rasmussen YH, Weber T, Kristensen B, Kehlet H. Effect of high-volume systemstic local infiltration analgesia in Caesarean section: a randomized, placebo-controlled trial. Acta Anaesthesiol Scand 2015;59:632–9.
[19] Hirstovska AM, Kristensen BB, Rasmussen MA, Rasmussen YH, Elving LB, Nielsen CV, et al. Effect of systematic local infiltration analgesia on postoperative pain in vaginal hysterectomy: a randomized, placebo-controlled trial. Acta Obstet Gynecol Scand 2014;93:233–8.
[20] Doyle DJ, Garmon EH. American society of anesthesiologists classification (ASA class). Treasure Island, FL: StatPearls Publishing; 2018 Available at: https://www.ncbi.nlm.nih.gov/books/NBK441940/ (last accessed 6 December 2018).
[21] McDowell I, Newell CA. Guide to rating scales and questionnaires. New York: Oxford University Press; 1987.
[22] Myles PS, Myles DB, Galagher W, Boyd D, Chew C, MacDonald N, et al. Measuring acute postoperative pain using the visual analog scale: the minimal clinically important difference and patient acceptable symptom state. Br J Anaesth 2017;118:424–9.
[23] Macbeth G, Razumiejczyk E, Ledesma RD. Cliff's delta calculator: a non-parametric effect size program for two groups of observations. Univ Psychol 2011;10:545–55.
[24] Romano J, Kromrey JD, Coraggio J, Skowronek J, Devine L. Exploring methods for evaluating group differences on the NSSE and other surveys: are the t-test and Cohen's d indices the most appropriate choices? Proceedings of the annual meeting of the Southern association for institutional research 2006.
[25] Goedhart J. Calculation of a distribution free estimate of effect size and confidence intervals using VBA/excel. , doi:http://dx.doi.org/10.1101/073999 bioRxiv the reprint server of biology. Available at: https://www.biorxiv.org/content/10.1101/073999v2.
[26] Venkatesh RR, Kumar P, Trissur RR, George SK. A randomized controlled study of 0.5% bupivacaine, 0.5% ropivacaine and 0.75% ropivacaine for supraclavicular brachial plexus block. J Clin Diagn Res 2016;10:UC09–12.
[27] Nolte H, Fruhstorfer H, Edstrom HH. Local anesthetic efficacy of ropivacaine (LEA 103) in ulnar nerve block. Region Anesth 1990;15:118–24.
[28] Margolis AS, Crisp CC, Morrison C, Pauls RN. Predicting pain levels following vaginal reconstructive surgery: who is at highest risk? Fem Pelvic Med Reconstr Surg 2018;24:172–5.