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GENERAL UROLOGY

Original Article

Low dose lignocaine + butorphanol vs. low dose bupivacaine for spinal anaesthesia in day care urological surgeries: a prospective randomized control trial

Günübirlik ürolojik cerrahilerde spinal anestezide düşük doz lidokain + butorfanola karşın düşük doz bupivakain: prospektif randomize kontrollü bir çalışma

Shahil Rameshbhai Khant, Rajeev Chaudhari, Rishikesh Arun Kore, Shirish Bhagwat, Ranjan Purushottam Jakhalekar

ABSTRACT

Objective: A local anaesthetic with fast onset, short and reliable duration of anaesthesia may be preferable for day care urological surgeries. Low dose lignocaine is believed to act faster and to have a shorter duration of action than low dose bupivacaine. Use of lignocaine for spinal anesthesia is discouraged now a days because of rare reports of transient neurological symptoms. The purpose of this study was to compare effectiveness and safety of low dose of lignocaine + butorphanol against low dose of bupivacaine for day care urological surgeries.

Material and methods: A prospective randomized control trial was conducted between December 2012 to November 2015. After taking ethical committe approval and patient consent, total 990 patients were randomized in two groups. Group A received 0.5 mL of 5% lignocaine (25 mg) + 0.3 mL butorphanol (0.3 mg) and group B received 1 mL of 0.5% bupivacaine (5 mg) for spinal anesthesia. Spinal anesthesia was given at the L3-L4 interspace with the patient in the sitting or lateral position. The criteria for evaluation were time till onset of sensory and motor block, duration of sensory and motor block, time till ambulation, time till fit for discharge and any complications.

Results: Both the groups were comparable in terms of age, male to female ratio, American Society of Anesthesiologists (ASA) grade and duration surgery. Group A and Group B were statistically different in terms of mean time till onset of sensory block (120±22 sec and 274±36 sec), onset of motor block (228±34 sec and 372±41 sec), duration of sensory block (100±21 min and 230±28 min), duration of motor block (60±15 min and 152±23 min), time till ambulation (138±24 min and 292±48 min), time till fit for discharge (256±35 min and 428±46 min) respectively (<0.0001). Nausea, vomitings, hypotension, bradycarida and pruritis were less in group A compared to group B (<0.01). None of patient in any group had temporary or permanent neurological defecit.

Conclusion: Spinal anaesthesia is an effective as well as a safe modality to anaesthetize the patient for day care urological procedures. This study shows lignocaine + butorphanol is preferable over bupivacaine for spinal anesthesia for day care urological procedures. It also favours day care surgery at remote areas with lesser medical facilities. It helps to minimize requirement of medical and paramedical staff, thus further extending scope of day care urological surgeries.

Keywords: Bupivacaine; day care urological surgeries; lignocaine + butorphanol; low dose drugs; spinal anesthesia.

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ÖZ

Amaç: Günübirlik ürolojik cerrahilerde hızlı başlangıçlı, kısa ve güvenilir süreli anestezi sağlayan bir lokal anestezik tercih edilebilir. Düşük doz lidokainin düşük doz bupivakaine göre daha hızlı etki ettiğine ve daha kısa etkili olduğu bilinir. Seyrek görülen geçici nörolojik semptomlar nedeniyle günümüzde spinal anestezide lidokain kullanımından kaçınılmaktadır. Bu çalışmanın amacı günübirlik ürolojik cerrahilerde lidokain + butorfanole karşın düşük doz bupivakainin etkinlik ve güvenliğini karşılaştırmaktı.

Gereç ve yöntemler: Bu prospektif randomize çalışma, Aralık 2012 ile Kasım 2015 arasında yürütülmüştür. Etik kurul onayı ve hasta onamını aldıktan sonra toplam 990 hasta iki gruba randomize edilmiştir. Spinal anestezi için Grup A'ya , 0,5 mL %5 lidokain (25 mg) + 0,3 mL butorfanol (0,3 mg) ve Grup B'ye 1 mL %0,5 bupivakain (5 mg) uygulanmıştır. Hasta oturur veya yan yatar pozisyondayken L3-L4 arasına spinal anestezi verilmiştir. Değerlendirme ölçütleri duysal ve motor blok oluşmaya başlayana kadar geçen zaman, duysal ve motor blokun süresi, hasta ayağa kalkana, taburcu olana ve herhangi bir komplikasyon oluşana kadar geçen zamandı.

Bulgular: Her iki grup yaş, erkek/kadın oranı, Amerika Anesteziyoloji Derneği (ASA) derecesi ve cerrahinin süresi açısından benzerdi. Grup A ve Grup B duysal ve motor blok başlangıcına kadar geçen ortalama süre (sırasıyla, 120±22 sn ve 274±36 sn'e karşın 228±34 sn ve 372±41 sn), duysal ve motor blokun süresi (sırasıyla, 100±21 dk ve 230±28 dk'e karşın 60±15 dk ve 152±23 dk) hasta ayağa kalkana ve taburcu olana kadar geçen zaman (138±24 dk ve 292±48 dk'a karşın 256±35 dkı ve 428±46 dk) bakımından istatistiksel açıdan farklıydı (<0,0001). Grup A'da bulantı, kusmalar, hipotansiyon, bradikardi ve pruritus Grup B'ye göre daha az görülmüştür (<0,01). Her iki grupta hiçbir hastada geçici veya kalıcı nörolojik defisit olmamıştır.

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Sonuç: Günübirlik ürolojik işlemler için kullanılan spinal anestezi hem etkili hem de güvenli bir yöntemdir. Bu çalışma günübirlik ürolojik cerrahilerde spinal anestezi için lidokain + butorfanolün kullanımının bupivakaine göre tercih edilebilir olduğunu göstermektedir. Ayrıca olanakları kısıtlı yerlerde günübirlik cerrahi işlemlerde kullanılabilir. Tıp ve paramedikal personel gereksinmesini en alt düzeye indirmeye yardımcı olmakta, böylece günübirlik ürolojik cerrahilerin kapsamını daha fazla genişletmektedir.

Anahtar Kelimeler: Bupivakain; günübirlik ürolojik cerrahiler; lidokain + butorfanol; düşük dozlu ilaçlar; spinal anestezi.

Introduction

The day care surgery or ambulatory surgery can be defined as admission of selected patients to the hospital in which patient undergoes an elective and planned procedure after which patient can be discharged on same day.[1] With advancements in lithotripsy, advent of slimmer endoscopes, developments in laser technology and better anaesthetic techniques, many urological procedures have been included in the horizon of day care urology (DCU). Part of the requirement for a successful day care surgery practice anywhere is the availability of good anaesthesia. A patient undergoing day care surgery must recover quickly from anaesthesia and ambulate early.[2] The major factor that restricts the widespread use of spinal anaesthesia in day care setting is prolonged postoperative recovery period or degree and effects of residual block.[3] Lignocaine appears to be ideal agent because of rapid and short duration of action with minimal side effects, but in past decade some reports of neurotoxicity have cast doubts on the use of lignocaine for spinal anaesthesia.[4] The use of lignocaine for spinal anesthesia is discouraged now a days because of rare reports of transient neurological symptoms. [5] Many attempts like using different drugs in varying doses, either as a sole drug or in combination have been made till date to overcome the prolonged postoperative residual block after spinal anaesthesia and to hasten the recovery. This include lignocaine, bupivacaine, alfentanyl, sufentanyl, butorphanol, fentanyl etc.[6-8] It was observed that in our hospital we use lignocaine for spinal anesthesia since many years without any major complications. We found that studies mentioned in literature comparing use of local anesthetic for spinal anesthesia have small sample size of patients.[9-11] The main purpose of this study was to evaluate effectiveness and safety of low dose lignocaine and bupivacaine with large sample size in day care urological practice.

The purpose of this study was to evaluate the effectiveness of evaluate the effectiveness of low dose of lignocaine (25mg) + butorphanol (0.3 mg) (0.5 mL of 5% lignocaine + 0.3 mL butorphanol) against low doses of bupivacaine (5 mg) (1 mL of 0.5% bupivacaine) for day care urological surgeries. The criteria for evaluation were time for onset of sensory and motor block, duration of sensory and motor block, time till ambulation, time till fit for discharge and any complications.

Material and methods

Study design

Ethical comitte approval was taken. Patient's consent were taken. It is prospective randomized controlled trial conducted at Department of Urology and urodynamics centre, Rahee health care between December 2012 to November 2015. Patients were randomly assigned to one of two groups.

Group A: 0.5 mL of 5% lignocaine + 0.3 mL butorphanol as spinal anaesthesia (Total dose: 25 mg lignocaine + 0.3 mg butorphanol).

Group B: 1 mL of 0.5% bupivacaine as spinal anaesthesia (Total dose: 5 mg).

Randomization was carried out using computer-generated simple random tables. Primary end point was to determine duration till patient was fit for discharge, after spinal anesthesia with above drugs. The effect size accepted for this parameter was r>0.5.

Study population

Total of 1088 patients between the ages of 19 to 76 years with American Society of Anesthesiologists (ASA) Grade I, II and selective Grade III patients were chosen for the day care urological surgery. Ninety-eight patients were excluded for different reasons (Figure 1). Patients undergoing day care urological surgery with expected surgical duration of less than 1 hr. Patients with coagulation abnormalities, cardiac disease or renal failure, deformities of the spinal column, local anesthetic allergies, those taking antiplatelet or anticoagulant medications, intraoperative conversion of spinal to general anesthesia, prolong surgical duration >1 hr.

Technique

The study population was divided in two groups A and B. Computer-generated simple random table was used. Spinal anaesthesia was given at the L3-L4 interspace (L4-L5 in case of failure) with the patient in the sitting or lateral position by using a 26 Gauge Quincke's spinal needle with a trocar. All patients were immediately placed in a supine position following the injection. We did not use ketamine or pentazocine in any of our patient.

Outcome assessment

Patients were monitored for blood pressure, oxygen saturation, heart rate and continuous electrocardiogram. Assessment of sensory block, which is defined by loss of sharp pain, is done by pinprick test. The pinprick test is done by using a 20 guaze hypodermic needle, at dermatomal levels in the midclavicular line on both the sides. The motor block was evaluated using the Bromage scale[12] to a desired scale of 3 (0 = no motor block, 1 = hip blocked, 2 = hip and knee blocked, 3 = hip, knee

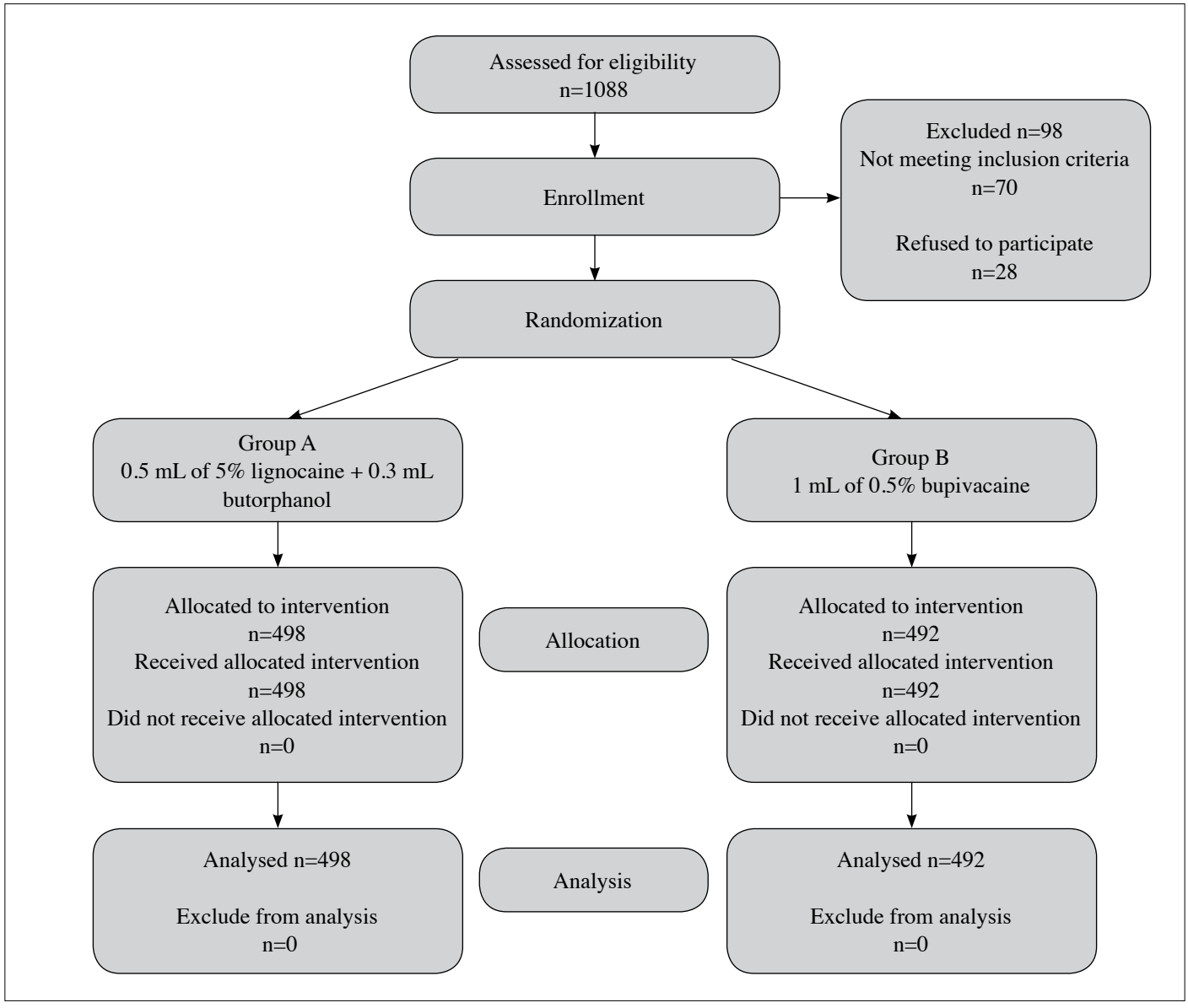

Figure 1. Consort diagram of the study

and ankle blocked). After the adequate spinal block has been achieved, the duration from infusion of the spinal anaesthetic agent till the readiness for surgery has been recorded. After this, the lithotomy or supine position was given to the patient as per the need of the procedure. Events like hypotension, bradycardia or respiratory depression were recorded. Symptoms if any, like pruritus, nausea, vomiting were noted. Any need of intravenous analgesics, sedatives or general anaesthesia was recorded. Postoperatively all the parameters were recorded at an interval of 30 minutes till the time of discharge. Patients were ambulated after complete recovery from motor and sensory block. Fitness for discharge was decided using following criteria.

1) Completely ambulatory patient.
2) Voided urine in toilet if not catheterized.
3) Complete recovery from motor and sensory block.
4) No nausea or vomiting.
5) Hemodynamically stable patient.

Discharged patients were advised to contact investigator in case of any complaint or symptoms.

Statistical analysis

Assuming margin of error 4%, confidence level of 99% and power of test 80% it was estimated that 986 patients would be required. Sample size was calculated using EPI Info version 'T' software.

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Results are expressed as mean values ± SD. The effect size accepted for primary end point (time duration till fit for discharge) was r>0.5. The calculations were performed with SPSS version 15.0 for Windows. The mean differences were compared using an unpaired Student's *t*-test. Data was analysed using Fisher's exact test or the Pearson's chi-squared test, where applicable. A p value of <0.05 was considered statistically significant.

Results

Group A consisted of 498 patients and group B consisted of 492 patients. Both the groups were comparable in terms of age in years, male to female ratio, ASA functional class of anaesthesia and duration of surgery in minutes (p value >0.05) (Table 1). Mean time till onset of sensory block was 120±22 seconds in group A and was 274±36 seconds in group B. Mean time till onset of motor block was 228±34 seconds in group A and was 372±41 seconds in group B (Figure 2). Mean duration of sensory block in group A was 100±21 min and in group B was 230±28 min. Mean duration of motor block was 60±15 min in group A and was 152±23 min in group B (Figure 3). Mean time duration when patients were ambulated after complete recovery of sensory and motor block was 138±24 min in group A and was 292±48 min in group B. The participants of group A were ambulated much earlier than those in group B. Among the patients in group A postoperative recovery, sensory as well as motor, was so quick that 180 (36%) patients of group A shifted themselves from operative table to the trolley with minimum assistance. However, such recovery was not seen in any patient from Group B. Mean duration when patients were fit for discharge was 256±35 min in group A and was 428±46 min in group B (Figure 4). The above result shows Group A has statistically significant (p<0.0001) quicker onset of sensory and motor block, shorter duration of sensory block and motor block, shorter duration till ambulation, shorter duration till discharge when compared with group B (Table 2). Effect size(r) of time duration till discharge is r=0.9. Among group A (n=498) 470 patients were discharged postprocedure on same day and remaining patients (n=28) were discharged on next

Table 1. Demographic data

	Group A (n=498)	Group B (n=492)	p
Age in years Mean±SD	50.06±15.22	52.45±14.89	0.14
Sex (Male/Female)	414/84	420/72	0.8164
ASA functional class (I/II/III)	200/228/70	175/287/30	---
Duration of surgery in minutes Mean±SD	46.08±32.52	50.63±31.16	0.44

ASA: American Society of Anesthesiologists; SD: standard deviation

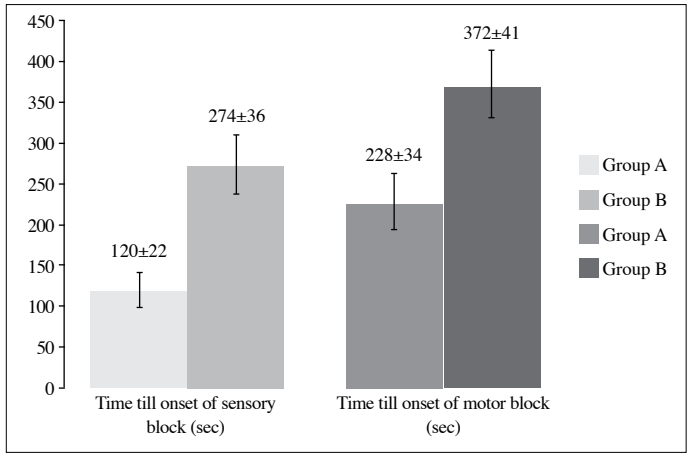

Figure 2. Distribution of onset of sensory and motor block

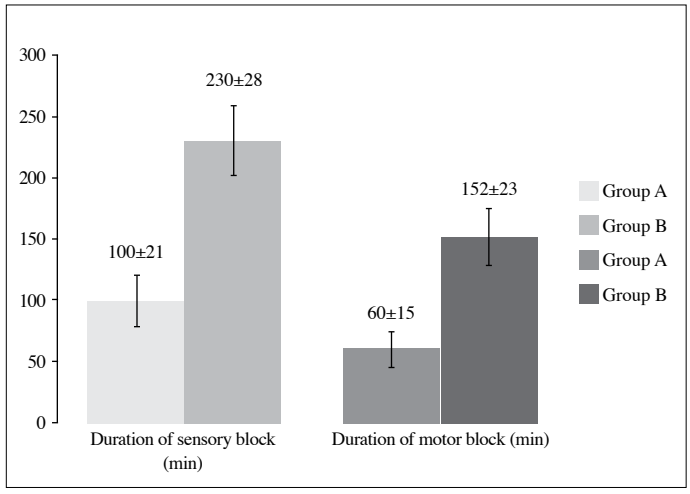

Figure 3. Distribution of duration of sensory and motor block in minutes

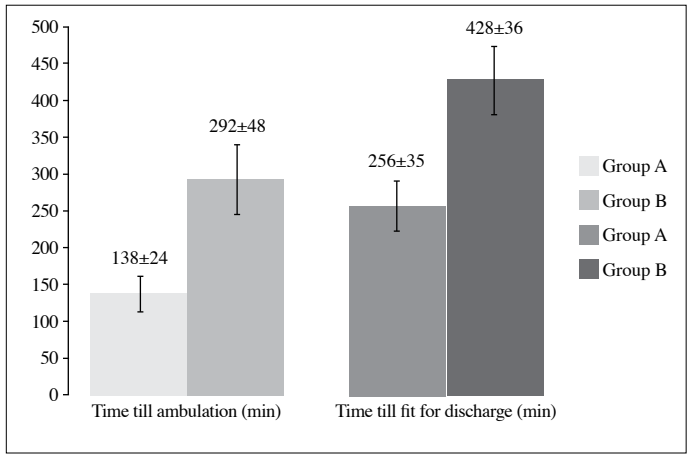

Figure 4. Distribution of time till ambulation and time till fit for discharge in minutes

day. This late discharges were due to surgical reasons like hematuria, fever, failue to void, etc. Among group B (n=492), 378 patients went home the same day and remaining 104 [54 were due to prolong anesthesia and 50 were due to surgical reasons] were discharged on next day. Nausea, vomitings, hypotension, bradycarida and pruritis were less in group A compared to group B (Table 3). None of patient in any group had temporary or permanent neurological defecit.

Discussion

The main purpose of this study was to evaluate effectiveness and safety of low dose lignocaine and bupivacaine with large sample size in day care urological module. This is a randomized control trial involving 990 patient. They were divided into Group A and Group B as mentioned above. To our knowledge, there are no published studies with sample size of 990 patients. In our study, both group A and group B were comparable in terms of age in years, male to female ratio of the participants, ASA functional class of anaesthesia and duration of surgery in minutes.

Mean time of onset for sensory block in our study was 120±22 sec for group A and 274±36 sec for group B (p<0.0001). Mean time till onset of motor block in our study was 228±34 seconds in group A and was 372±41 seconds in group B (p<0.0001). In a study by Punj et al.[10], only 20 patients were studied in each group. They used 2 mL of 5% lignocaine (100 mg) and 2 mL of 0.5% bupivacaine (10 mg).The mean time for onset of sensory block and motor block was shorter in their study due to higher volume and dose of drug used (Table 4).[13]

In our study group A has significantly shorter duration of sensory and motor block (p<0.0001). In a study by Williams et al.[11] total 30 patients were studied which were randomized into two groups (3.5 mL of 2% lignocaine and 3 mL of 0.5% bupivacaine). Though doses of drugs used were higher (70 mg lignocaine and 15 mg bupivacaine) in study by Williams et al.[11], onset of sensory block was longer when compared to our study.[11] This difference can be attributed to the technique of assessing sensory block which was assessed by ethylene chloride spray.[14] Mean duration of sensory and motor block was higher in their study due to higher doses of drug used when compared with our study (Table 4).[11]

In study by Patra et al.[9] total 75 patients were randomized into 3 groups of 25 patients each.The groups varied according to doses of bupivacaine. One of the group received bupivacaine 5 mg + 25 microgram of fentanyl for endoscopic urological surgeries. Dose of bupivacaine was same as in our study, but 25 microgram of fentanyl was added with bupivacaine. Mean time for onset of sensory block (323±132 sec) was comparable with our study. Duration of sensory block, motor block and time till fit for discharge was less when compared with our study. In our study mean duration after which patients were fit for discharge was 256±35 min in group A and 428±46 min in group B which is statistically significant. Among group A (n=498) 470 patients were discharged postprocedure on same day and remaining patients (n=28) were discharged on next day. This late discharges were due to surgical reasons like hematuria, fever, failue to void, etc. Among group B (n=492), 378 patients went home the same day and remaining 104 (54 were due to prolong anesthesia and 50 were due to surgical reasons) patient were discharged on next day.

Spinal anaesthesia with lignocaine has been popular for short surgical procedures as it has predictable onset and provides dense sensory and motor block of moderate duration. The choice is based on a record of more than several decades of its safe use. Unfortunately, in the past decade some reports of neurotoxicity have cast doubts on the use of lignocaine for spinal anaesthesia.[4,5] Consequently some authors warn against its use for spinal anaesthesia. The phenomenon of transient neurologic symptoms (TNS) may be associated with all local anaesthetics but it is 7-9 times higher following lignocaine than with bupivacaine.[15] The etiology of TNS remains unclear and unproven. It is important to note that

Table 2. Comparison of parameters between group A and group B

	Group A n=498	Group B n=492	p
Time till onset of sensory block (sec)	120±22	274±36	<0.0001
Time till onset of motor block (sec)	228±34	372±41	<0.0001
Duration of sensory block (min)	100±21	230±28	<0.0001
Duration of motor block (min)	60±15	152±23	<0.0001
Time till ambulation (min)	138±24	292±48	<0.0001
Time till fit for discharge (min)	256±35	428±46	<0.0001
Patients discharged on same day	470	378	<0.0001

Table 3. Comparison of complications between groups A and B

Symptom	Group A n=498	Group B n=492	p
Nausea	9 (1.8%)	24 (4.87%)	0.007
Vomiting	13 (2.61%)	27 (5.48%)	0.02
Pruritis	8 (1.6%)	23 (4.67%)	0.005
Hypotension	27 (5.42%)	55 (11.1%)	0.001
Bradycardia	22 (4.41%)	45 (9.14%)	0.003
Headache	2 (0.4%)	5 (1.01%)	0.25
Neurological defecit	0	0	

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Table 4. Comparison of our study with other studies

	Group	Our study*	Punj et al.[10]**	Williams et al.[11]***	Patra et al.[9]#
Time till onset of sensory block (sec)	Lignocaine	120±22	62.5±25.05	180	
	Bupivacaine	274±36	79.5±52.26	540	323±132
Time till onset of motor block (sec)	Lignocaine	228±34	119.5±56.51		
	Bupivacaine	372±41	137.25±60.92		702±246
Duration of sensory block (min)	Lignocaine	100±21	133.6±17.68	135	
	Bupivacaine	230±28	172.5±49.64	295	205.71±41.12
Duration of motor block (min)	Lignocaine	60±15	110±27.76	104	
	Bupivacaine	152±23	159.25±53.49	182	75.75±31.04
Time till ambulation (min)	Lignocaine	138±24			
	Bupivacaine	292±48			
Time till fit for discharge (min)	Lignocaine	256±35			
	Bupivacaine	428±46			239.3±40

*0.5 mL of 5% lignocaine (25 mg) + 0.3 mL butorphanol and 1 mL of 0.5% bupivacaine (5 mg).

**2 mL of 5% lignocaine (100 mg) and 2 mL of 0.5% bupivacaine (10 mg).

***3.5 mL of 2% lignocaine (70 mg) and 3 mL of 0.5% bupivacaine (15 mg).

#bupivacaine 5 mg + 25 microgram of fentanyl.

after nearly a century of use, it is only now being recognized as an adverse effect of spinal anaesthesia.[16] Study done using lignocaine as spinal anesthesia does not show any transient neurologic symptoms.[7] Our study also does not show transient neuroloic symptoms in any of our patients. In our study both Group A and Group B have produced adequate anaesthesia in all the 990 participants who were posted for urological procedure as a day care surgery. Our study shows Group A is statistically better than Group B in terms of time till onset of sensory block, time till onset of motor block, duration of sensory block, duration of motor block, duration till ambulation ,postoperative recovery sensory as well as motor, no of patients discharged on same day. No major complications were noted in both groups. Comparison of our study with other studies is given in (Table 4).[9-11]

In conclusion, spinal anaesthesia is an effective as well as a safe mode to anaesthetize the patient for day care urological procedures. This study shows 0.5 mL of 5% lignocaine + 0.3 mL butorphanol over 1 mL of 0.5% bupivacaine as preferred anesthesia for day care urological procedures. Main advantage of using 0.5 mL of 5% lignocaine + 0.3 mL butorphanol is early motor and sensory function recovery and thus early discharge. It also favours day care surgery at remote areas with lesser medical facilities and minimum requirement of medical and paramedical staff thus further extending scope of day care urological surgeries. Hence we recommend spinal anesthesia with 0.5 mL of 5% lignocaine + 0.3 cc butorphanol over 1 mL of 0.5% bupivacaine as preferred anesthesia for day care urological procedures.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Department of Urology and Urodynamics Centre, Rahee Health Care.

Informed Consent: Written informed consent was obtained from patient who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – S.R.K., R.C.; Design – R.C. ; Supervision – R.C., S.B., R.P.J.; Resources – R.C., S.R.K., R.A.K.; Materials – R.C., R.A.K.; Data Collection and/or Processing – S.R.K., R.C., R.A.K.; Analysis and/or Interpretation – S.R.K., R.C., R.P.J.; Literature Search – R.C., S.R.K., R.A.K.; Writing Manuscript – S.R.K., R.A.K.; Critical Review – R.C., S.R.K., R.A.K, R.P.J., S.B.; Other – R.C., S.B.

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