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ORIGINAL PAPER

# The effects of method of anaesthesia on the safety and effectiveness of Radical Retropubic Prostatectomy

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## Summary

***Objective:*** *The aim of this study is to determine if patients undergoing radical retropubic prostatectomy with localized prostate cancer under combined (epidural-spinal) anaesthesia have any benefit over patients undergoing the procedure under general anaesthesia.*

***Material and Methods:*** *Patients with clinically localised prostate cancer, scheduled for radical retropubic prostatectomy, were allocated to undergo the operation under either general anaesthesia (GA) or under combined (epidural-spinal) (CESA) anaesthesia. Several parameters were recorded both preoperatively (medical history, biometric data, PSA, biopsy Gleason score) and postoperatively (blood pressure, heart rate, haemoglobin levels, operation time and total hospital stay). In addition, mean arterial pressure, change in heart rate, total blood loss, blood transfusions, SAS score, intravenous fluid administration and operation time were also noted down intraoperatively. Patient pain levels and total satisfaction were evaluated using appropriate questionnaires. At the 12-month follow-up, biochemical recurrence using PSA levels and urinary continence status were evaluated.*

***Results:*** *A total of 60 patients were included (30 in each group). Intraoperatively, mean MAP and heart rate change was higher in the GA group (MAP+7,46, HR+27) and mean SAS was higher in the CESA group (+0.93). The time needed for patients' recovery was faster (-3.5 min) and hospitalization was shorter for patients in the CESA group (-0.6 days). Intraoperative blood loss, time for induction and duration of operation were not significantly different. Mean postoperative drop of haemoglobin was greater in the GA group (+0.56) while blood transfusions, VAS pain scores and amount of intravenous fluids did not differ significantly between the two groups. No complications were reported. Patient satisfaction and urinary continence were comparable between the groups and there were no cases of biochemical recurrence.*

***Conclusions:*** *Radical retropubic prostatectomy can safely be performed under combined (spinal epidural anaesthesia, with possible benefits of lower blood loss, less post-operative complications and earlier discharge. Both procedures have equal oncological and functional outcomes at the 12-month follow-up.*

***KEY WORDS:*** *Prostatic neoplasm; Radical prostatectomy; Complications; Combined anaesthesia.*

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## INTRODUCTION

Prostate cancer (PCa) is the most common neoplasm in men and accounts for 27% of all cancers diagnosed (1). In developed countries, population awareness and wide *Prostatic Specific Antigen* (PSA) screening has resulted in an early on-set detection, with most cases being discovered as localized disease and therefore being eligible for definitive therapy, including radical prostatectomy or radiotherapy (2). Surgical excision of the prostate may be carried out either with a retropubic open approach or with the laparoscopic or robot-assisted technique (2).

The goal of radical prostatectomy, is eradication of the disease with preservation of continence and erectile functions (3). Due to high-costs of acquiring and maintaining robotic equipment, the retropubic open approach is still being practiced alongside newer methods worldwide, providing excellent results in patient survival rates and quality of life (4).

In this study we aimed to evaluate two methods of anaesthesia (general and combined epidural-spinal) in patients undergoing open retropubic radical prostatectomy and define whether these may have an impact on the oncological outcome and safety of the procedure.

## MATERIALS AND METHODS

The study was conducted at the 2nd Urology University Department of Sismanoglio Hospital in Athens Greece, from August 2020 to July 2022, after being approved by the Institutional Review Board of the Hospital.

Patients with clinically localized PCa and eligible for *Radical Retropubic Prostatectomy* (RRP), were preoperatively allocated to receive either *Combined Epidural and Spinal Anaesthesia* (CESA) or *General Anaesthesia* (GA).

All patients were preoperatively informed about both methods of anaesthesia and signed a consent form. Patients with a medical history of severe heart disease, haemostasis disorders, previous pelvic surgery and lung disease were excluded from the study.

A *Body Mass Index* (BMI) value was calculated for all patients, preoperatively, as weight in kg divided by squared height in meters (kg/m$^2$). There are 4 BMI categories Underweight (< 18.5), Normal weight (18.5-24.9), Overweight (25-29.9) and Obesity (> 30).

No conflict of interest declared.

Patients in the GA group were premedicated with intravenously administered (IV) midazolam (2 mg) and fentanyl (100 mcg). A simple oxygen mask was applied. Induction was performed using IV propofol (2.5-3 mg/kg) and lidocaine (40 mg); at that time dexamethasone 8 mg, metoclopramide 10 mg and omeprazole 40 mg were also administered. After successful tracheal intubation, Total Intravenous Anaesthesia (TIVA) was maintained by administering propofol (0.05 mg/kg/sec IV) and remifentanil (0.2 mcg/kg/sec iv). Pain management was achieved by administering paracetamol (1g IV) and ramadol (100 mg iv) whereas muscle relaxation was obtained by vecuronium (0.6 mg/kg IV).

CESA group was performed using an epidural 18G needle and a spinal 27G needle, which were inserted in the L2-L3 or L3-L4 interspace. Induction was carried out by spinal intrathecal administration of levobupivacaine (2.6-3ml of 0.5%) whereas mild sedation was achieved by midazolam (5 mg IV in bolus). All patients were administered dexamethasone 8 mg, metoclopramide 10 mg and omeprazole 40 mg IV, at that time. Maintenance was performed 75 minutes after induction and obtained using an epidural administration of levobupivacaine (4-5 ml of 0.5%). An epidural catheter was maintained until successful completion of the procedure and removed in the recovery room. The medications used for both types of anaesthesia are presented in Table 1.

All patients in both groups received a standard postoperative regimen of intravenous paracetamol (1 g x 4 for the first 2 days) and cefoxitin (1 g x 3 until discharge); a prophylactic dose of enoxaparin was also given subcutaneously for 2 weeks, starting from postoperative day 2. If a patient was experiencing pain that could not be alleviated using the standard analgesic regimen, extra tramadol was administered on demand and recorded by the reviewer.

Several parameters were recorded intra- and postoperatively. The time (minutes) required for induction of anaesthesia, the operation time and the total postoperative time (defined as that required for patients' recovery, i.e., from completion of the operation to patient transfer to the recovery room) were noted down. Intraoperative haemodynamic status was constantly being monitored by measuring *systolic pressure* (SP) and *diastolic arterial pressure* (DP) and heart rate every 15 minutes; the *Mean Arterial Pressure* (MAP) was also being calculated using the formula MAP=DP+1/3(SP-DP). Haemoglobin levels, both preoperative and at specific times postoperatively (at the $12^{th}$, $24^{th}$ and $48^{th}$ postoperative hours) were also measured. In addition, total blood loss (litres of fluid collected by suction during surgery which were categorised in < 100 ml, 100-600 ml and > 1000 ml), fluids administered intravenously during surgery (in litres) and the *Surgical Apgar Score* (SAS) (5) were calculated. Postoperatively, total hospitalization days, patient pain intensity using the *Visual Analogue Scale* (VAS) and any need for extra analgesics were recorded. VAS is based on a linear "*zero*" (No pain) to "*ten*" (*Worst Pain Possible*) scale. Patients were asked to quantify their pain on that scale, at three different postoperative time points (after 6, 24, and 48 hours). Complications from the cardiovascular and respiratory systems as well as those related to the anaesthetic techniques were recorded; in addition, postoperative headache, nausea and vomiting and any signs of potential nerve damage (manifested as inability to gain leg motility) were also assessed and recorded before hospital discharge (6, 7). All patients upon discharge filled in a *Short Assessment of Patient Satisfaction* (SAPS) Questionnaire (8) measuring their overall satisfaction for the care they received. In SAPS, satisfaction is measured in a scale of 0 to 28, with 0 to 10 equals to "*Very Dissatisfied*", 11-18 equals to "*Dissatisfied*", 19-26 equals to "*Satisfied*" and 27-28 equals to "*Very Satisfied*".

Patients were followed for up to 12 months postoperatively. PSA levels were measured at the $6^{th}$ and $12^{th}$ month to record a potential biochemical recurrence. At the same time, patients were asked to assess their urinary continence by completing the *International Consultation on Incontinence Questionnaire* (9) - *Urinary Incontinence Short Form*.

Statistical analysis was carried out using SPSS 24.0. Mean values, standard deviations, median values, *Interquartile Range* (IQR) and histograms were used to describe quantitative variables whether the data followed the normal distribution. Collected data for systolic blood pressure, diastolic blood pressure, heart rate and haemoglobin were used with new quantitative variables being created by calculating the differences between the aforementioned time-points for each one of these variables. The Kolmogorov-Smirnov test was run to check the normality of the distributions. The Student's t-test or the non-parametric Mann-Whitney U test were used to compare quantitative variables between the two groups, depending on whether the data followed the normal distribution. A Kruskal-Wallis test (nonparametric equivalent of the one-way ANOVA) was used to make comparisons among the BMI-categories in CESA and GA group. Moreover, linear or logarithmic models were used to check for differences between the studied groups, taking into account other factors (e.g., demographic and clinical characteristics). In case of asymmetrical distribution, logarithmic transformations of the variables were used. Significance levels were bilateral and the statistical significance were set at $p < 0.05$.

## Results

Overall, 60 patients were included in the Study (30 in each group). Both groups were demographically compa-

***Table 1.***
*Anaesthetic techniques in the study groups.*

| Anaesthesia stage | Combined epidural - Spinal anaesthesia | General anaesthesia |
|---|---|---|
| Premedication | None | Midazolam 2 mg bolus IV<br>Fentanyl 100 mcg bolus IV |
| Induction | Levobupivacaine 0.5% 2.6-3cc Spinal intrathecal<br>Midazolam 5 mg IV<br>Dexamethasone 8 mg IV<br>Metoclopramide 10 mg IV<br>Omeprazole 40 mg IV | Lidocaine 40 mg bolus IV<br>Propofol 2,5-3 mg/kg bolus IV<br>Dexamethasone 8 mg IV<br>Metoclopramide 10 mg IV<br>Omeprazole 40 mg IV |
| Maintenance | Levobupivacaine 0.5% 4-5cc epidural | Propofol 0.05 mg/kg/sec IV<br>Remifentanil 0.2 mcg/kg/sec IV<br>Paracetamol 1 g IV<br>Tramadol 100 mg IV<br>Vecuronium 0.6 mg/kg IV |
| Recovery room | Paracetamol 1g IV | Paracetamol 1g IV |

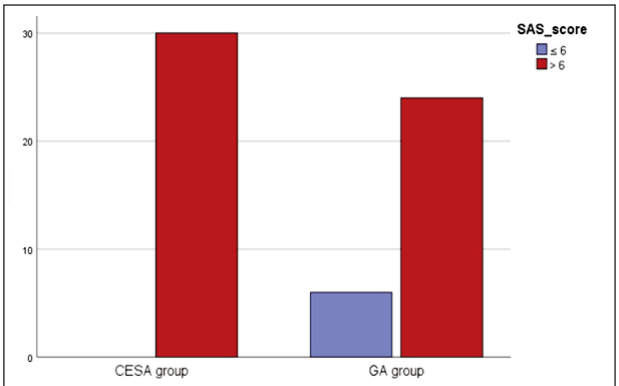
*IV = Intravenous; mg = Milligram; g = Grams; kg = Kilograms; mcg = Microgram.*

***Table 2.***
*Demographic and oncological characteristics of patients.*

| Demographics | CESA (n = 30) Mean ± SD | GA (n = 30) Mean ± SD | 95% CI, p-value |
|---|---|---|---|
| Age (years) | 66.93 ± 5.66 | 66.40 ± 4.89 | (-3.42, 4.49), 0.78 * |
| Height (m) | 1.72 ± 0.078 | 1.75 ± 0.044 | (-0.08, 0.01), 0.140 * |
| Weight (kg) | 78.8 ± 10.57 | 81.87 ± 14.96 | (-12.75, 6.62), 0.52 * |
| ASA physical status (II/III) | 23/7 | 20/10 | NS ** |
| Preoperative PSA (ng/ml) | 6.81 ± 3.06 | 8.01 ± 2.78 | (-3.38, 0.99), 0.27 * |
| Gleason Score | | | NS ** |
| 6 | 6/30 | 4/30 | |
| 3+4 | 10/30 | 8/30 | |
| 4+3 | 8/30 | 10/30 | |
| 8 | 6/30 | 7/30 | |
| 9 | 0/30 | 1/30 | |

*CESA = Combined Epidural and Spinal Anaesthesia; GA = General Anaesthesia; ASA = American Society of Anaesthesiologists; PSA = prostate-specific antigen; NS = non-significant. * Independent samples t-test. ** Pearson Chi-square test.*

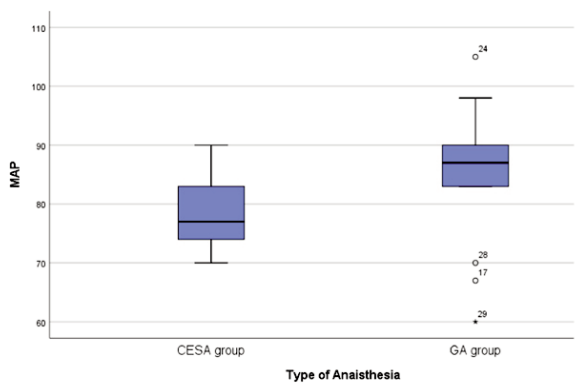
***Figure 2.***
*SAS scores in the CESA and GA groups.*




*CESA = Combined Epidural and Spinal Anaesthesia; GA = General Anaesthesia; SAS = Surgical APGAR score; MAP = Mean Arterial Pressure.*

rable and homogeneous with regard to age, height, weight, smoking habit, alcohol use, history of diabetes mellitus, biopsy Gleason Score and preoperative PSA. Preoperative characteristics are presented in Table 2.
Intraoperative MAP was found to be significantly higher in the GA group [85.13 ± 11.84] *vs.* CESA group [77.67 ± 5.66] (p = 0.036) (Figure 1). Furthermore, patients in the GA group exhibited higher heart rate intraoperatively when compared to the preoperative measurement, as opposed to those in the CESA group who exhibited lower heart rate than the preoperative measurement (GA: +25 (17), CESA: -2 (7), (p < 0.01). Intraoperative blood loss, as collected by the suction, did not differ significantly between the two groups. Time for anaesthesia induction was identical in both groups (13.6 ± 3.5 min in the CESA group *vs.* 13.6 ± 2.9 min in the GA group, p > 0.05). Duration of the operation in the CESA and GA groups was 127 ± 17.29 min and 126.33 ± 10.93 min, respectively (p > 0.05). However, the time needed for patients' recovery and transfer to the recovery room was significantly shorter in the CESA group (16.13 ± 4.9 min) as compared to that in the GA group (19.6 ± 3.5) (p = 0.03).

***Figure 1.***
*MAP values in the CESA and GA groups.*




*CESA = Combined Epidural and Spinal Anaesthesia; GA = General Anaesthesia; SAS = Surgical APGAR score; MAP = Mean Arterial Pressure.*

Statistically significant difference was also noticed in the mean intraoperative SAS (8.13 ± 0.63 in the CESA group *vs.* 7.2 ± 1.37 in the GA group, p < 0.03). A SAS score ≤ 6 was recorded in 6 patients (20%) in the GA group in comparison to none in the CESA Group (Figure 2). Hospitalisation was significantly shorter for patients in the CESA group compared to those of the GA group (2.6 ± 0.5 *vs.* 3.2 ± 0.41, respectively, p = 0.003).
Postoperative mean drop of haemoglobin was 1.5 ± 0.81 in the CESA group *vs.* 2.06 ± 1.1 in the GA group (p = 0.029), indicating a statistically significant difference in blood loss in favour of the combined anaesthesia. Blood transfusion was required in 1 patient in the CESA group and 2 patients in the GA group (p = 0.54). VAS score was found to be equal between the two groups and all patients reported only mild pain 48 hours after the surgery, contrary to moderate and severe pain reported on the day of surgery and 24 hours after. Data regarding haemoglobin changes and VAS score are listed in Tables 3, 4.

***Table 3.***
*Haemoglobin change within the first 48 hours.*

| Hb change | CESA group Mean ± SD | GA group Mean ± SD | p-value * |
|---|---|---|---|
| Pre-op/Post-op | -2.06 ± 1.1 | -1.5 ± 0.81 | 0.029 |
| 24h - after surgery | -0.9 ± 0.59 | -1.18 ± 0.84 | 0.305 |
| 48h - 24h | -0.28 ± 0.73 | -0.48 ± 0.71 | 0.439 |
| 48h - after surgery | -1.18 ± 0.66 | -1.67 ± 0.93 | 0.113 |
| 48h - before surgery | -3.24 ± 1.19 | -3.18 ± 1.19 | 0.771 |

*Pre-op: Pre operatively; Post-op: Post operatively. * Independent samples t-test.*

***Table 4.***
*VAS Score within the first 48 hours.*

| VAS | CESA group | GA group | p-value * |
|---|---|---|---|
| Day of surgery | 6.47 ± 0.51 | 6.53 ± 0.51 | 0.720 |
| 24h after surgery | 5.13 ± 0.51 | 5 ± 0.53 | 0.487 |
| 48h after surgery | 3.2 ± 0.41 | 3.33 ± 0.48 | 0.417 |

*SD: standard deviation; CESA: combined epidural spinal anaesthesia; GA: general anaesthesia; VAS: Visual Analog Scale. * Independent samples t-test.*

No complications were reported across any group and none of the patients in the CESA group reported either post-subarachnoid puncture headache or any nerve damage or difficulty in regaining leg motility. In the CESA group, there was no case with a need for the anaesthesia to be dynamically converted to GA during surgery. Additional postoperative analgesic requirements as well as the daily amount of intravenous fluids did not differ significantly between the two groups, (CESA: 2933 ± 703.7 ml daily *vs.* GA: 3000 ± 845.15 ml, p = 0.945).
All patients in both groups reported to be satisfied with the care they received (p > 0.05); also regain of urinary continence was comparable between the two groups after 12 months. Lastly, there were no cases of biochemical recurrence in either group at the 6$^{th}$ and 12$^{th}$ postoperative months.
When participants were sub-analysed according to BMI categories, there were no underweight patients, 24 of normal weight (CESA: 10, GA: 14), 26 overweight (CESA: 16, GA: 10) and 10 obese patients (CESA: 4, GA: 6). A higher heart range change was observed in obese patients in the GA group when compared to overweight and normal patients (32 *vs* 25 and 23, respectively; p = 0.002). There was no difference of statistical importance between any other factors, when comparing each BMI group of GA. In the CESA BMI groups, there were no statistical differences for any of the factors.

## Discussion

In this comparative study, all patients undergoing RRP for organ-confined PCa under either general or combined (epidural and spinal) anaesthesia were safely treated and discharged without any major complications. Time for induction of anaesthesia and surgical time were the same in both groups. In addition, no post-subarachnoid puncture headaches, nerve damages or difficulty in regaining leg motility were recorded in the CESA group whereas no cases of vomiting and/or postoperative delirium were found in the GA group.
In the GA group, intraoperative heart rate was recorded higher and there was a greater drop in the post-operative mean haemoglobin value, when compared to the CESA group, potentially indicating a greater blood loss in patients under GA. Nonetheless the amount of fluids retrieved by the suction was similar in both groups, hence one has to assume that a greater amount of blood was held within the gauzes during surgery. This parameter however was not measured in our study. *Shir Y et al.* (10) also demonstrated mean intraoperative blood loss to be significantly higher in patients undergoing surgery under GA compared to those receiving epidural anaesthesia (respective mean values 1940 and 1490 litres) and similar in those receiving combined general/epidural anaesthesia (mean 1810 litres); they concluded that epidural anaesthesia did not reduce bleeding, it was rather the administration of GA that increased intraoperative haemorrhage (10). The authors recognised positive pressure ventilation to be a potential contributing factor, due to the increase in intrathoracic pressure and decrease in venous return to the heart that causes (11), which in turn results in increased peripheral venous pressure (12) and consequent increased bleeding during surgery (13). However, contrary to the results of *Shir Y et al.*, we found no difference in blood transfusions between the 2 groups. Significantly lower blood loss with combined epidural/GA, compared to general alone, was also reported by others (14, 15).
SAS was statistically different between the groups, with patients in the CESA group having an overall higher mean score, indicating a potentially reduced risk for postoperative complications. It is noteworthy that a SAS score < 6, which is deemed a threshold for increased risk for major complications, was reported in 20% of patients in the GA group, compared to none in the CESA group. This potentially implies a greater risk for postoperative complications in those receiving GA. Postoperative complications may delay not only patients' recovery and discharge from hospital but also return to their normal activities with an overall reduction in their quality of life (16). Nevertheless, the potential safety benefits of CESA over GA, need to be further investigated in larger-scale studies.
Both groups reported equal VAS scores, with higher pain levels reported immediately after surgery and a constant reduction thereafter. In the literature, there have been reports indicating lower pain levels in patients receiving CESA. *Dunet F et al.* (15) demonstrated an improvement in required postoperative analgesics, within the first 48 hours, in patients undergoing RRP under combined general/epidural anaesthesia over patients receiving GA alone. This observation however, was not confirmed in the present study.
Patients receiving CESA remained in the operating theatre for a shorter period of time (average -3.5 minutes), compared to those receiving GA, and furthermore their hospitalisation was significantly shorter (-0.6 days). A shorter operating theatre and hospital stay is beneficial for both patients and Health Services alike, because it reduces patients' exposure to specific pathogens, reduces anxiety and, at the same time, reduces costs (15, 17). By streamlining the CESA technique for RRP, the duration of surgery will further decrease, leaving time for more operations, thereby increasing hospital incomes (18). Medical economics are equally important to other aspects of Medicine and treatment options, apart from being personalized, should be cost-effective (19). In general, application of techniques which enable provision of the best health care possible, while reducing risks of hospital-acquired infections and at the same time, requiring less funds, is of great importance.
Overall satisfaction at the time of discharge was similar in both groups and after a one-year of follow-up, no biochemical recurrences and no difference in the incidence of urinary incontinence, were reported. These results, which are in line with other reports (20), indicating that both methods of anaesthesia are safe to perform with equal oncological and functional results.
BMI is another important factor that may potentially influence various parameters during the operation. We have noticed a higher intraoperative HR change in obese patients receiving GA, compared to those in the CESA group. This finding, combined with the higher drop in the mean postoperative haemoglobin level, may indicate a greater blood loss in obese patients. However, due to the

small number of obese patients (10) included in the study, no clear inference can be drawn on this issue. *Cai T et al.* (21), in their study of 78 patients undergoing radical prostatectomy, reported an increased blood loss in obese patients compared to patients with normal weight; nonetheless the differences were not statistically significant. In contrast to our results, *Cai et al.* also found that obese patients were significantly more likely to have urinary incontinence postoperatively compared to non-obese patients, a finding not observed in our study.
Lastly, it should be noted that the data presented in this study apply only to patients undergoing open radical prostatectomy and not to those undergoing laparoscopic or robotic procedures. A potential advantage of either form of anaesthesia in these procedures should be investigated in separate studies.

## Conclusions

Open RRP carried out under combined spinal/epidural anaesthesia is a safe procedure to perform and is associated with less intraoperative blood loss and potentially reduced risks of postoperative complications. It may lead to a shorter total operation time and reduced hospitalization, while providing similar oncological and functional outcomes. Further studies are needed to reliably confirm the substantial role of combined anaesthesia in this major oncological operation.

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