

Anesthesia for MVA in Resource-Limited Setting: Comparative Study of Ketamine Narcosis versus Intrathecal Analgesia in the DRC

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How to cite this paper: Ntamusimwa, S.I., Fefe, R.I., Sengeyi, D., Risasi, J.-R.M., Munyali, D.A., Zalambo, S.S., Milinganyo, E.W., Namegabe, F.Z. and Nsimire, B.B. (2024) Anesthesia for MVA in Resource-Limited Setting: Comparative Study of Ketamine Narcosis versus Intrathecal Analgesia in the DRC. *Open Journal of Anesthesiology*, **14**, 258-275.

<https://doi.org/10.4236/ojanes.2024.141203>

Received: September 5, 2024

Accepted: December 14, 2024

Published: December 17, 2024

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Abstract

Introduction: The current recommendations for manual vacuum aspiration (MVA) for incomplete abortion, although not different in terms of effectiveness of the anesthetic techniques of choice, have still shown some inadequacies which have stimulated the search for an alternative technique which can be effective, such as microdose intrathecal spinal analgesia that can be recommended in limited resources environment. **Aim:** This work aims to contribute to the improvement of anesthetic techniques for incomplete abortion by MVA. **Methodology:** We conducted a prospective comparative study, type single blind non-inferiority randomized trial with an analytical aim. The study counted 2 parts: 1) Descriptive observational component (KET): Ketamine narcosis. 2) Experimental component, single-blind non-inferiority randomized clinical trial (RAS) microdose intrathecal spinal analgesia. Three hundred and twenty expected cases per randomized arms. Excel Software 2022, SPSS, Open Epi, and XL-SAT were used for data encoding and analysis. **Results:** A total of 322 cases were retained and analyzed: 1) 161 cases per randomized arm, the majority age group was between 18 - 50 years in the 2 groups and there was no correlation between the two. Protocols with the sociodemographic characteristics studied, ASA class, type of intervention, history of MVA, variation in heart rate, temperature, appearance of hypotension, cost of

the anesthetic procedure and admission to intensive care. 2) Effectiveness of the RAS protocol: Judged easier by anesthesiologists at 99.38% compared to 93.79% for KET with significant difference ($p = 0.0104$), allows them to be more mobile during the procedure at 98.76 % against 68.32% with significant difference ($p < 0.0001$) and the overall assessment was in favor of the RAS protocol at a rate of 32.92% against 5.58% for the anesthesiologists, 90.68% for the patients and 100% for gynecologists who find it excellent compared to the KET protocol with significant difference ($p < 0.0001$). 3) Weaknesses of the KET protocol: unconsciousness in all patients during the procedure and provides more tachypnea (17.39%) compared to the RAS protocol with difference $p = 0.0008$, moderate hemorrhages (55.28%), severe (9.94%) with $p = 0.0006$, higher material cost with $p = 0.0018$, occurrence of vomiting (10.56%), delay in waking up (22.36%), post-MVA pain (21.74%), and a slight change in the modified Aldrete score at the 30th min post-MVA (70.19%) compared to RAS (81.61%) $p = 0.0002$. 4) No patient died during the study period in both protocols. Conclusion: Intrathecal spinal analgesia microdosed with bupivacaine 0.1% and Fentanyl 50 $\mu\text{g}/\text{cc}$ according to the process used in this study, has proven its effectiveness compared to Ketamine narcosis, currently recommended and not different in terms of effectiveness from other anesthetic techniques recommended for MVA indicated for incomplete abortion and can therefore be recommended as the anesthetic practice of choice in this area in a resource-limited setting.

Keywords

Anesthesia, Ketamine Narcosis, Intrathecal Analgesia

1. Introduction

Anesthesia for manual vacuum aspiration (MVA) is a hot topic in research in gynecology-obstetrics. It is indicated in incomplete abortion for hemostatic purposes as it's a health problem throughout the world [1]. As reported by the World Health Organisation (WHO), it concerns 20 million pregnancies and approximately 78,000 maternal deaths due to it each year around the world [2].

Approximately 5 million pregnancies are complicated each year by 34,000 maternal deaths in Africa [3]. To reduce the morbi-mortality, WHO recommends MVA as gynecological practice [4] and narcosis and paracervical block as anesthetic practices [5] for incomplete abortion. A study done in South Kivu (DRC) in 2020 on "inventory of anesthetic practice for endo-uterine evacuation" concluded that WHO current recommendations are respected but the morbi-mortality is relatively high and that opened a necessity of proposal for another anesthetic practice which could solve the problem. It's in that order that intrathecal spinal analgesia with a posological formula based on weight and height of patients, of 0.1% bupivacaine and fentanyl was proposed as an alternative [6].

It was necessary to compare that to objective judgment criteria, the efficacy of

ketamine narcosis (KET) and intrathecal spinal analgesia (RAS) with main objective to contribute to the improvement anesthetic ECP of incomplete abortion by MVA and specific objectives to determine the sociodemographic, epidemiological and clinical profile of patients, to compare the two practices in terms of analgesic effectiveness, comfort, financial cost and risk of complications occurred and at last to present the levels of satisfaction of patients and practitioners in relation to the two protocols (KET and RAS).

2. Methods

1) Type of Study

This is a prospective comparative study with an analytical aim on 2 parts:

- Descriptive observational aspect with analytical aim (KET): Ketamine Narcosis observation and data collection.
- Experimental component as double-blind randomized non-inferiority clinical trial (RAS): Application of the RAS protocol to improve their practice.

2) Sampling

We want to have exhaustive probability samples for both phases of data collection. The samples will be grouped into 2 study groups:

- KET group: (Neutral): All patients benefiting from endo-uterine aspiration under ketamine narcosis in the selected hospitals will be concerned by this observational phase.
- RAS group: (Witness): All consenters after being informed to do part of the study adhering to the RAS protocol will be affected by this experimental phase.

But, to calculate the estimated size of the sample which should give us statistically reliable results, we proceeded to the average of the results of the sample sizes obtained using the software OpenEpi, XLSTAT and which statistical calculation by the formula of the size of the sample recommended for comparisons of proportions (here our two randomized arms KET and RAS). For all these calculations by software and through the formula, we took the standard power of 80% and a standard error of 5% with a prevalence of KET patients of 32.5% and RAS of 60% in accordance with the literature results for MVA post-abortum.

Thus, the sample sizes were:

- (1) For the Open Epi software: $N' = 116$.
- (2) For the XLSTAT software: $N'' = 268$.

$$(3) \text{ For the formula comparing proportions } N = \frac{2 \times \bar{P}(1 - \bar{P})(Z_{\alpha/2} + Z_{\beta})^2}{(P_1 - P_2)^2}$$

=162 cases or 81 cases per randomized arm.

With:

- P_1 : Proportion of patients for whom the judgment criteria are equal to 1 (100%) in group 1 (KET).
- P_2 : Proportion for which the judgment criteria are worth 1 (100%) in group 2 (RAS).
- \bar{P} : Average proportion of patients for whom the judgment criteria are equal to

1 (100%) in the 2 groups (KET and RAS).

• $Z/2$ and Z : Constants determined by and therefore $(Z/2$ and $Z)^2$ is also a constant determined by the power (1-) and the type I error allowing the null hypothesis to be rejected (H_0).

$1 - \beta$		70%	80%	90%	95%	99%
α	= 5%	6.2	7.8	10.5	12.9	18.4
	= 1%	9.6	11.7	14.9	17.8	20.1
$(Z \alpha/2 + Z\beta)^2$						

By applying the formula for our study:

• P_1 : 0.325 (KET prevalence for MVA 32%) (25)

• P_2 : 0.60 (Spinal analgesia prevalence for MVA 60%) (25)

$$\bullet P = \frac{0.32 + 0.60}{2} = 0.46$$

• $(Z\alpha/2 + Z\beta)^2 = 7.8$ (because power 80%) and Type I error (5%)

• $(P_1 - P_2)^2 = (-0.28)^2 = 0.0784$

$$N_i = \frac{2 \times 0.46 \times (1 - 0.46) \times 7.8}{0.0784} = 49.45 \approx 50 \text{ cases/Randomized arm}$$

Hence TOTAL = 100 cases

$N''' = 100$ cases

By averaging the 3 sample sizes we find:

$$N = \frac{N' + N'' + N'''}{3} = \frac{116 + 268 + 100}{3}$$

=162 cases or 81 cases per randomized arm

Taking into account the cluster effect linked to the multicentricity of our study, the inflation factor (IF) allows us to have a sample size to circumvent this flu effect by maintaining as follows

$$FI = [1 + (n - 1)]$$

With: n = Average size of a cluster (81 for our study)

p = Interclass correlation coefficient (0.01 for our study because our main judgment criteria are results type)

$$FI = [1 + (81 - 1) \cdot 0.01] = 1.8$$

Hence, the size of our sample after eliminating the flu effect becomes:

$$N_{\text{cor}} = N \cdot FI = 162 \cdot 1.8 = 291.6$$

And adding 10% loss:

$$N_{\text{+at}} : N_{\text{cor}} + 10\%N_{\text{cor}} = 291.6 + 29.16 = 320.32$$

≈ 320 cases or 160 cases / randomized arm

3) Inclusion Criteria

• **KET phase:** All patients who received post-abortion endo-uterine aspiration

in the selected hospitals during the observational period.

•**RAS phase:** All patients who, after informed consent, agreed to try the RAS protocol for post-abortion endo uterine aspiration in selected hospitals.

4) Exclusion and Non-Inclusion Criteria

(a) **Exclusion criteria:** Patient refusal.

(b) **Non-inclusion criteria:** Any patient, who has benefited from post-abortion endo-uterine aspiration using protocols other than KET and RAS, Patients who received post-abortion endo-uterine aspiration by KET or RAS outside the data collection period.

5) Data Collection and Analysis

The descriptive analysis was carried out using proportion calculations for qualitative variables (frequencies, percentages) and means with their standard deviation (SD) for quantitative variables. Sociodemographic and clinical characteristics as well as patient morbidity were compared between the two anesthetic protocols administered (KET and RAS) using chi-square tests for categorical variables and Student's t-test for continuous variables. The data were encoded in an Excel 2022 software mask and analyzed using STATA statistical software (version 16.0). P-values less than 0.05 were considered statistically significant.

6) Variables Studied and Judgment Criteria

(a) Variables

•**Independent variables:** Age, profession, province, hospital of care, ASA class.

Dependent variables: Temperature, Heart rate, respiratory rate, anesthetic protocol, SPO₂, nausea, vomiting, delay in waking up, cost of hospital stay post uterine aspiration, Simple verbal pain scale, preparation time, anesthesia time, site of puncture, level of sensory block, modified Aldrete score.

(b) Judging Criteria

•**Main:** Analgesic effectiveness, patient and practitioner comfort.

•**Secondary:** Cost, morbi-mortality, complication, duration of post-MVA surveillance.

7) Ethical Considerations

The human materials and data were performed in accordance with the declaration of Helsinki and we received the ethical committee approval referenced UOB/CEM/09/2022.

8) Expected Impact

Adoption and popularization of the RAS protocol with hypobaric Bupivacaine 0.1% and microdose fentanyl adapted to weight and size according to the formulas proposed by this study to contribute to the reduction of morbidity and mortality of post-arbotum endometrial aspirations (incomplete spontaneous abortion) in DRC and elsewhere.

3. Results

The size of our final sample retained and analyzed is 161 KET cases and 161 RAS cases) or 100.6% of the calculated sample size of 320 cases that were attended. This

satisfactory percentage will therefore be able to give us reliable results to compare the 2 protocols KET and RAS according to the set objectives (**Figure 1**).

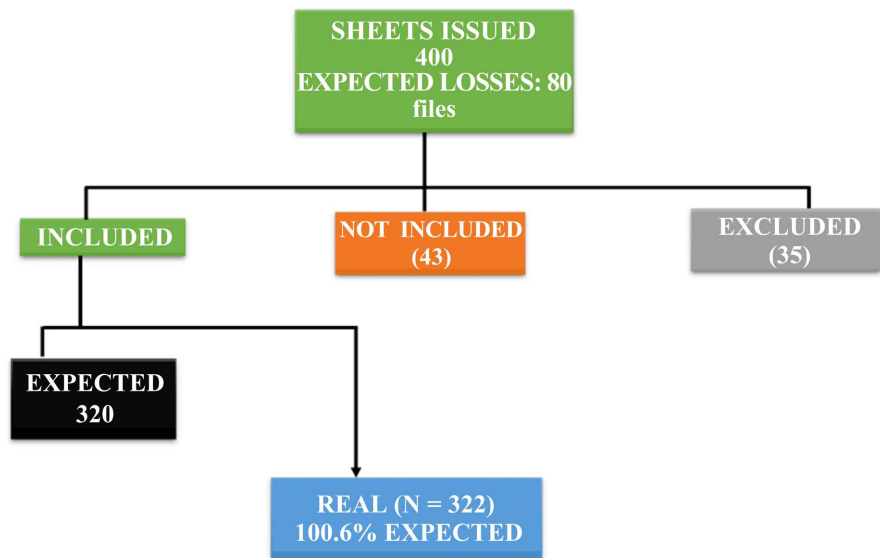


Figure 1. Flowchart of data collection summary.

3.1. Sociodemographic, Epidemiology and Clinical Characteristics

a) Distribution of Patients according to Hospital Structures.

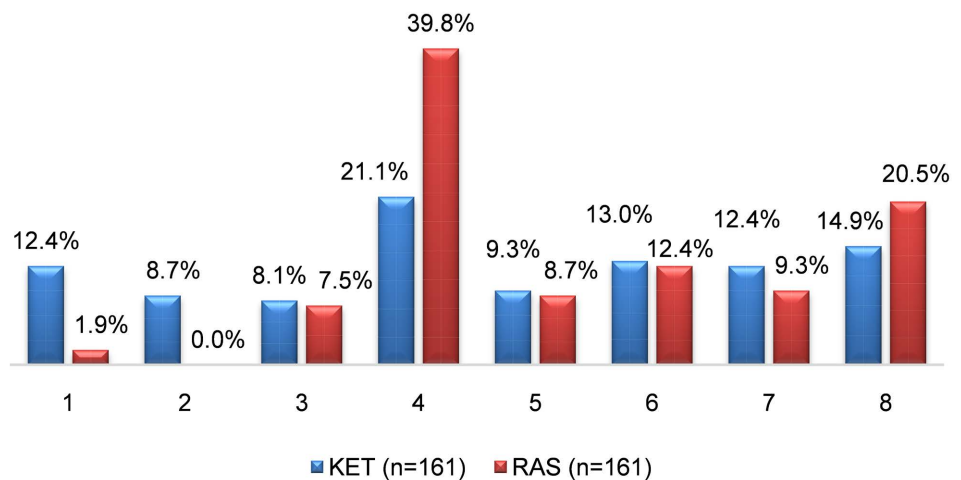


Figure 2. Distribution of patients according to hospitals according to the operating protocol.

Figure 2 shows the use of KET and RAS anesthetic protocols in the eight hospitals selected for this study.

Significant variations are observed between the hospitals: hospital 4 had mostly used the RAS protocol (39.75%) compared to KET (21.12%), while hospital 2 had not used the RAS protocol. Other hospitals, such as hospitals 1, 3, 5, 6 and 7, used the KET protocol much more than the RAS protocol.

b) Sociodemographic and Epidemiology Characteristics.

Table 1. Correlation between sociodemographic characteristics and anesthetic protocol.

Variable	Anesthetic Protocol				p-value
	KET (n = 161)		RAS (n = 161)		
Age					0.2420
<18 years	18	11.18%	13	8.07%	
18 - 50 years	143	88.82%	146	90.68%	
>50 years	0	0.00%	2	1.24%	
Provenance					0.4534
Urban	150	93.17%	154	95.65%	
Rural	11	6.83%	7	4.35%	
Education level					0.2274
Primary	18	11.18%	14	8.70%	
Secondary school	84	52.17%	73	45.34%	
Superior/university	59	36.65%	74	45.96%	
Marital status					0.7600
Mary	109	67.70%	114	70.81%	
Bachelor	45	27.95%	42	26.09%	
Divorced	7	4.35%	5	3.11%	
Profession					0.7809
Housekeeper	81	50.31%	77	47.83%	
None	46	28.57%	39	24.22%	
Employee	25	15.53%	32	19.88%	
Entrepreneur	9	5.59%	13	8.07%	
Religion					0.7271
Protestant	72	44.72%	75	46.58%	
Catholic	59	36.65%	56	34.78%	
Atheist	22	13.66%	17	10.56%	
Muslim	6	3.73%	9	5.59%	
Animist	2	1.24%	4	2.48%	

Table 1 presents the sociodemographic characteristics of the patients according to the anesthetic protocol used. The sociodemographic characteristics of the patients, including age, origin, level of education, marital status, profession and religion, did not show statistically significant differences between the two anesthetic protocols (KET and RAS) ($p > 0.05$).

c) Clinical Characteristics

Table 2. Comparison between clinical characteristics and anesthetic protocol.

Variable	Anesthetic Protocol				p-value
	KET (n = 161)		RAS (n = 161)		
Parity, Mean ± SD	2.39 ± 2.13		2.76 ± 2.20		0.1298
Weights, Mean ± SD	66.45 ± 11.08		69.24 ± 11.85		0.0288
Size, Average ± ET	162.06 ± 8.89		162.61 ± 9.71		0.5946
BMI, Mean ± SD	25.34 ± 4.24		26.24 ± 4.24		0.0600
Classification ASA					0.9082
I	69	42.86%	64	39.75%	
II	61	37.89%	61	37.89%	
III	22	13.66%	23	14.29%	
IV	8	4.97%	12	7.45%	
V	1	0.62%	1	0.62%	
Type Of Intervention					0.5996
Urgent	125	77.64%	121	75.16%	
Programmed	36	22.36%	40	24.84%	
Background of MAV					0.9027
No	114	70.81%	113	70.19%	
Yes	47	29.19%	48	29.81%	
Heart Rate					0.1539
Bradycardia	4	2.48%	4	2.48%	
Normal	109	67.70%	124	77.02%	
Tachycardia	48	29.81%	33	20.50%	
Respiratory Rate					0.0008
Bradypnea	9	5.59%	11	6.83%	
Normal	124	77.02%	143	88.82%	
Tachypnea	28	17.39%	7	4.35%	
Temperature					0.188
Hypothermia	5	3.11%	7	4.35%	
Normal	153	95.03%	154	95.65%	
Fever	3	1.86%	0	0.00%	
Blood Pressure					0.0985
Hypotension	30	18.63%	34	21.12%	
Normal	111	68.94%	118	73.29%	
Hypertension	20	12.42%	9	5.59%	

Continued

Oxygen Saturation					0.2187
Desaturation	9	5.59%	4	2.48%	
Normal	152	94.41%	157	97.52%	
Reanimation					0.6193
1 - 24 h	5	3.11%	4	2.48%	
24 - 48 h	11	6.83%	6	3.73%	
>48 Hours	4	2.48%	5	3.11%	
Don't Do	141	87.58%	146	90.68%	
Type of Bleeding					0.0006
Light	56	34.78%	85	52.80%	
Moderated	89	55.28%	72	44.72%	
Severe	16	9.94%	4	2.48%	

Table 2 compares the clinical characteristics between the KET and RAS anesthetic protocols. There was no significant difference between the two groups in terms of average parity (2.39 for KET and 2.76 for RAS; $p = 0.1298$). Patients under RAS have a slightly higher mean weight (69.24 kg) compared to those under KET (66.45 kg), with a p value of 0.0288, indicating a statistically significant difference. As for the mean height of the patients, there is no significant difference between the two protocols ($p = 0.5946$). The average BMI is slightly higher for RAS (26.24) compared to KET (25.34; $p = 0.0600$), but not statistically significant.

The distributions of the ASA classifications (I to V) are similar between the two protocols ($p = 0.9082$), indicating that there is no significant difference in the ASA risk levels between KET and RAS. The distribution between urgent and scheduled interventions is comparable for the two protocols ($p = 0.5996$), suggesting that the type of intervention does not differ significantly between KET and RAS.

There is no significant difference between the two groups in terms of history of MVA ($p = 0.9027$), indicating that the antecedents are distributed in a similar manner. The p value of 0.1539 indicates that there is no significant difference in heart rate between the two protocols; the majority of patients have a normal heart rate, with some cases of bradycardia or tachycardia.

There is a significant difference ($p = 0.0008$) in the respiratory frequency between the protocols. Patients under RAS have fewer cases of tachypnea (4.35%) compared to KET (17.39%), while cases of bradypnea are slightly more frequent for RAS. Body temperatures are generally normal for the two protocols ($p = 0.188$), indicating that there is no significant difference between the groups in terms of body temperature.

The p value of 0.0985 indicates that there is no significant difference in blood pressure measurements between KET and RAS; the cases of hypotension and hypertension are distributed similarly between the two protocols. Oxygen saturation

levels are also comparable between the two protocols with a p value of 0.2187, indicating that there is no significant difference.

The resuscitation admission rates are also similar between KET and RAS ($p = 0.6193$), suggesting that there is no significant difference in post-operative resuscitation needs. Furthermore, there is a significant difference ($p = 0.0006$) in the type of bleeding between the two protocols. Patients with RAS have a higher percentage of light bleeding (52.80%) compared to KET (34.78%), while severe bleeding is more frequent with KET (9.94%) compared to RAS (2.48%).

3.2. Analgesic Effectiveness and Comfort for Patients and Practitioners

Table 3. Correlation between efficacy and anesthetic protocol.

Variable	Anesthetic protocol				p-value
	KET (n = 161)		RAS (n = 161)		
To The Anesthesiologist					
Facility					0.0104
Yes	151	93.79%	160	99.38%	
No	10	6.21%	1	0.62%	
Mobility					<0.0001
Yes	110	68.32%	159	98.76%	
No	51	31.68%	2	1.24%	
Appreciation					<0.0001
Bad	8	4.97%	1	0.62%	
Good	112	69.57%	62	38.51%	
Very Good	32	19.88%	45	27.95%	
Excellent	9	5.59%	53	32.92%	
To the Patient					
EVA Or EVS					<0.0001
None	0	0.00%	149	92.55%	
Light	0	0.00%	12	7.45%	
Unconsciousness	161	100.00%	0	0.00%	
Anxiety					0.2592
Yes	73	45.34%	63	39.13%	
No	88	54.66%	98	60.87%	

Continued

Appreciation					<0.0001
Bad	161	100.00%	0	0.00%	
Very Good	0	0.00%	15	9.32%	
Excellent	0	0.00%	146	90.68%	
By the Gynecologist					
Facility					0.0001
Yes	140	86.96%	158	98.14%	
No	21	13.04%	3	1.86%	
Relaxation					<0.0001
Yes	114	70.81%	154	95.65%	
No	47	29.19%	7	4.35%	
Appreciation					<0.0001
Bad	161	100%	0	0.00%	
Excellent	0	0.00%	161	100%	

Table 3 evaluates the effectiveness of KET and RAS anesthetic protocols according to several criteria for anesthetists, patients and gynecologists. The results show significant differences between the two protocols in several aspects.

For the ease of the technique among anesthesiologists, the RAS protocol is considered easier, with 99.38% of anesthesiologists finding it simple to use against 93.79% for KET. This difference is statistically significant with a p value of 0.0104. In terms of mobility, RAS is also superior, with 98.76% of anesthetists finding that this protocol allows better mobility against 68.32% for KET, with a p value of <0.0001. The global appreciation is more positive for RAS, with 32.92% of anesthetists finding it excellent against 5.59% for KET. The difference is very significant with a p value <0.0001.

Regarding the patients, the evaluation of pain during the act was not done for the KET protocol because the patients were unconscious but for the RAS protocol 92.55% reported that they had no pain and 45% reported that they had mild on EVS scale. The difference is therefore significant between the unconsciousness reported induced by the KET protocol in relation to the RAS and the analgesic efficacy evaluated by EVS of the RAS protocol in relation to the KET protocol with p < 0.001.

For gynecologists, the RAS protocol is perceived as offering better ease of AMIU, 98.14% finding it easy with RAS against 86.96% with KET, with a p value of 0.0001. RAS is also associated with better relaxation, with 95.65% of gynecologists finding this protocol relaxing against 70.81% for KET, with a p value

<0.0001. In terms of global appreciation, RAS is considered excellent by 100% of gynecologists, while KET is perceived as bad in 100% of cases, with a p value of <0.0001.

Figure 3 indicates significant differences between the KET and RAS anesthetic protocols regarding the patient's assessment of pain as measured by the EVS (simple verbal scales) with a p-value of <0.0001. For the KET protocol, 100% of the patients (161 cases) were unconscious during the MVA. On the other hand, for the RAS protocol, 92.55% of patients (149 cases) reported no pain, while 7.45% (12 cases) reported mild pain. No patient under the RAS protocol was unconscious.

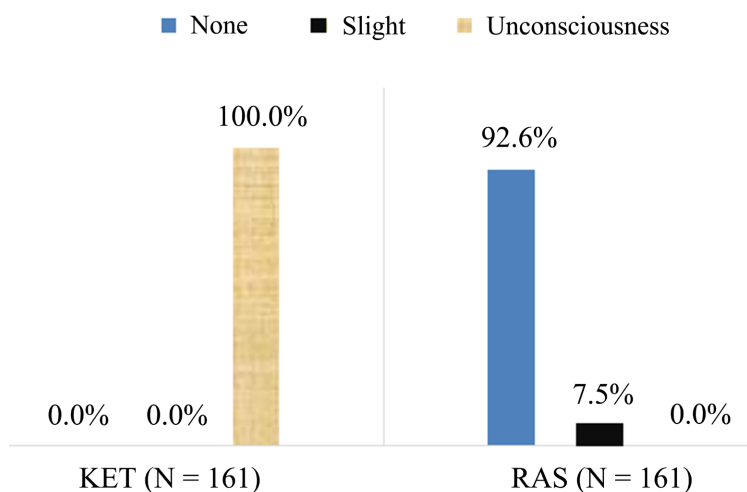


Figure 3. Evaluation of the condition of patients measured by the EVS according to the KET and RAS anesthetic protocols.

3.3. Costs of Materials and Anesthetic Procedures

Table 4 shows the comparison between the two protocols regarding the cost of acts and that of materials and products. The majority of acts for the two anesthetic protocols are in the cost range of 50 to 100 USD, with 54.66% for KET and 45.34% for RAS, indicating a tendency to concentrate costs in this category. For the costs of material and products, the majority is between 20 and 50 USD for the two protocols, with 65.22% for KET and 52.80% for RAS, showing a preference for moderate costs. For low-cost acts (<50 USD), RAS is slightly more used (31.68%) compared to KET (27.95%). Moderately priced acts (100 - 200 USD) are more often associated with RAS (22.98%) than with KET (16.77%). High-cost events (>200 USD) are rare for both protocols, with only 0.62% for KET and none for RAS. The p value of 0.2275 suggests that there is no statistically significant difference between the costs of procedures for the two anesthetic protocols.

RAS is more often associated with low-cost material (<10 USD) at 20.50% against 5.59% for KET. On the other hand, KET is more frequently linked to moderate costs (10 - 20 USD) at 19.25% against 14.91% for RAS. The two protocols

have similar percentages for expensive equipment (50 - 100 USD), with 9.32% for KET and 10.56% for RAS, and show low occurrences for very expensive equipment (100 - 200 USD), with 0.62% for KET and 1.24% for RAS. The p-value of 0.0018 indicates a statistically significant difference in material and product costs between the two protocols.

Table 4. Correlation between cost and anesthetic protocol.

Costs	Anesthetic protocol				p-value
	KET (n = 161)		RAS (n = 161)		
Proceedings					0.2275
<50	45	27.95%	51	31.68%	
50 - 100 units	88	54.66%	73	45.34%	
100 - 200 USD	27	16.77%	37	22.98%	
>200 USD	1	0.62%	0	0.00%	
Material and products					0.0018
<10 USD	9	5.59%	33	20.50%	
10 - 20 USD	31	19.25%	24	14.91%	
20 - 50 USD	105	65.22%	85	52.80%	
50 - 100 USD	15	9.32%	17	10.56%	
100 - 200 USD	1	0.62%	2	1.24%	

3.4. Morbi-Mortality

Table 5 correlates the complications that occurred with the KET and RAS anesthetic protocols. We found that nausea is slightly more frequent with the KET protocol (15.53%) compared to RAS (11.18%), but this difference is not statistically significant ($p = 0.2515$). Vomiting is significantly more frequent with KET, with 10.56% of cases against only 0.62% with RAS. The p value of <0.0001 indicates a very significant difference, showing that KET is associated with a much higher risk of vomiting. The incidence of shock is also similar between the two protocols, with 13.66% for KET and 14.29% for RAS. The p value of 1,000 indicates that there is no significant difference in the frequency of crashes. The occurrence of Mendelson's syndrome is identical for KET and RAS, with 1.24% in both groups. The p value of 1,000 shows that there is no significant difference. Pain is more frequent with KET (21.74%) compared to RAS (10.56%), and the difference is statistically significant with a p value of 0.006, indicating that KET is associated with a higher risk of pain after MVA. The bleeding frequency is identical for the two protocols, with 16.77% in the two groups. The p value of 1,000 indicates that there is no significant difference. The results show a different distribution between the protocols in relation to the delay in positive evolution of the modified Aldrete score at the 30th minute in SSPI with only 70.19% KET against 81.61% with RAS ($p = 0.002$).

Table 5. Correlation between occurrence of complications and anesthetic protocol.

Variable	Anesthetic protocol				p-value
	KET (n = 161)		RAS (n = 161)		
Nausea					0.2515
Yes	25	15.53%	18	11.18%	
No	136	84.47%	143	88.82%	
Vomiting					<0.0001
Yes	17	10.56%	1	0.62%	
No	144	89.44%	160	99.38%	
Delayed Awakening					<0.0001
Yes	36	22.36%	0	0%	
No	125	77.64%	161	100%	
Extended Block					1.000
Yes	0	0%	2	1.24%	
No	161	100%	159	98.76%	
Shock					1.000
Yes	22	13.66%	23	14.29%	
No	139	86.34%	138	85.71%	
Mendelson's Syndrome					1.000
Yes	2	1.24%	2	1.24%	
No	159	98.76%	159	98.76%	
Pain After MVA					0.006
Yes	35	21.74%	17	10.56%	
No	126	78.26%	144	89.44%	
Hemorrhage					1.000
Yes	27	16.77%	27	16.77%	
No	134	83.23%	134	83.23%	
Modified Aldrete Score					0.0002
<5	13	8.07%	10	6.21%	
5 - 9	35	21.74%	19	12.18%	
>9	113	70.19%	132	81.61%	

4. Discussion

4.1. Demographic, Epidemiology and Clinical Characteristics

Our study revealed that the age range between 18 and 50 years old was the predominant age range as our first study of state of affairs revealed that it was between 26 and 35 years old with an average age of 30 ± 7.5 years [1]. Even Ousmane O.K.

et al. found an age range between 20 and 25 years as the majority [6] but Padian in England found an average age of 29 years [7]. These similarities of ages comprised globally between 18 and 50 years old are explained by the fact that this age range is associated with the period of fertility in the woman from where the high frequency of MVA for incomplete abortion in this age range but everything like the other sociodemographic parameters studied in our study, age did not show a statistical correlation with the two protocols KET and RAS.

Class ASA I (RAS 42.8% and KET 39.7%) was predominant in the two groups during our study but without statistical correlation with the latter which correspond to what was found in our study on the status [1] where ASA I represented 91.4% of patients and in the study of Barreina Vielepily who found 85.4% for ASA I [8] and this similarity is explained by the alert that raises the bleeding during the incomplete abortion but also due to the fact that our studies are all conducted in urban environments where the level of education of women is quite high to identify the signs of danger and consult early.

The respiratory frequency within our study was the vital parameter that proved a correlation with the anesthetic protocols, *i.e.*, more bradypnea (6.83%) for the RAS protocol and more tachypnea (17.39%) for the KET protocol with $p = 0.0008$.

This tachypnea observed in the KET protocol during this study would explain desaturation as a respiratory complication that occurred (2.5%) and which was linked to mortality ($p < 0.0001$) in our first state-of-the-art study [1] whereas for the bradypnea observed during the protocol during the RAS protocol, it could be due to the comfort and relaxation that this technique entails, especially since it did not require respiratory support.

Our results in this study showed a correlation between mild bleeding and the RAS protocol and moderate to severe bleeding in the KET protocol ($p = 0.0006$). This may be explained by the pharmacokinetics and pharmacodynamics of the anesthetic products used in the two protocols.

4.2. Analgesic Effectiveness and Comfort for Patients and Practitioners

In our study, the RAS protocol was the only one to allow the objective evaluation of pain by EVS because the patients were all conscious, unlike the KET protocol where they were all unconscious during the procedure. The RAS protocol revealed that 92.55% of patients had no pain and 7.45% had mild pain during and after MVA in post-intervention care room, while the KET protocol was correlated to pain post-MVA plus that the RAS protocol ($p < 0.0001$). This would be explained by the fact that in the KET protocol there is no post-MVA analgesic given to the patients, while in the RAS protocol the addition of fentanyl prolongs the action of local anesthetics in relation to thermo-algesique sensibility abolished by intrathecal spinal analgesia. That joins the studies of Lamine M.D. in Mali [6] and Lauretti et Coll in Brazil [9] who respectively found that the patients did not need analgesics until 25 ± 8 hours after spinal analgesia because they had morphine as an adjuvant.

As for comfort, our results showed that the RAS protocol was judged easier to perform by 99.38% of the anesthetists ($p = 0.0104$), giving 98.76% of the anesthetists more mobility during the procedure ($p < 0.0001$), it facilitates the act of MVA for 98.14% of obstetrician-gynecologists, it is more relaxing for 98.65% of obstetrician-gynecologists and it is rated excellent by 90.68% of patients, 100% of obstetricians and 32.92% of anesthesia practitioners ($p < 0.0001$). This is explained by the ease and speed of the technique of spinal anesthesia and which is the same on the technical level in spinal analgesia which differs from it by the dilution of anesthetic products selectively targeting the sensitive fibers (ends of the spinal cord) but also the patients remain awake and can be released from the post-intervention monitoring room a few minutes after the manual vacuum aspiration (MVA) where they have no foot or no pain and are foot agitated which in the KET protocol makes the task easy for the gynecologist and obstetrician as well.

4.3. Costs

There was no statistical difference in relation to the cost of the anesthetic act in our study, but on the other hand, the material cost in the KET protocol is higher in relation to that in the RAS protocol with a statistically significant difference ($p = 0.0018$).

This is explained by the fact that, classically, the material to achieve a loco-regional microdose like intrathecal spinal analgesia according to the procedure practiced in this study is less because the hemodynamic and respiratory repercussions due most often to the sympathetic block are minimized by the dilution selectivity depending on the sensitive C fibers of the spinal cord for local anesthetics such as bupivacaine 0.1% used in our protocol.

4.4. Morbi Mortality

During our study, no patient died in either protocol. Nevertheless, our data reveals that the KET protocol is more promising and statistically linked to the occurrence of complications such as vomiting (10.56%), delayed awakening (22.366) and delayed positive evolution of the modified Aldrete score at the 30th minute in post-intervention monitoring room (70.19% KET against 81.61% RAS) with ($p = 0.002$). This seems to differ from the spinal analgesia protocols used by Lamine M.D in Mali [6] Chang-Jong Chung *et al.* in Korea [10] and Douiri H. *et al.* [11] who respectively had a frequency of 37% in the protocol with Néostigmine and 17% in the protocol without neostigmine, 40% with and 60% without neostigmine and even by reducing the dose of Neostigmine Douiri H and Coll. found that this did not reduce the frequency of nausea and vomiting. This would be explained by the fact that morphine combined with neostigmine could increase the risk of nausea and vomiting because all of them were emitting. For the delayed awakening and the modified Aldrete Score, this can be explained by the pharmacokinetics and pharmacodynamics of Ketamine and Diazepam which were used in the KET protocol.

5. Conclusions

At the end of this study, which had the general objective of contributing to the improvement of the anesthetic protocol for incomplete abortions by MVA and specifically to determine the sociodemographic, epidemiological and clinical profile of patients benefiting from MVA post-abortion in DRC, to compare the anesthetic techniques RAS and KET to deduce the effectiveness and finally to present the degrees of satisfaction of patients and practitioners of MVA post-abortion, the results come out that:

- A total of 322 cases were retained and analyzed, or 161 cases were randomized. The majority age group was between 18 - 50 years in the 2 groups KET and RAS and there was no correlation between the two protocols with the sociodemographic characteristics studied, the ASA class, the type of intervention, the history of MVA, the variation of heart rate, of the temperature, the appearance of hypotension, the cost of the anesthetic act and the intensive care unit admission.

- Efficacy of the RAS protocol: judged easier by the anesthetists in 99.38% against 93.79% for KET with significant difference ($p = 0.0104$), it allows them to be more mobile during the act in 98.76% against 68.32% with a significant difference ($p < 0.0001$) and the global appreciation was in favor of the RAS protocol in 32.92% against 5.58% for the anaesthetists, 90.68% for patients and 100% for gynecologists who find it excellent in relation to the KET protocol with a significant difference ($p < 0.0001$)

- KET protocol weaknesses: unconsciousness in all patients during the act and more tachypnea (17.39%) compared to the RAS protocol with difference $p = 0.0008$, moderate bleeding (55.28%), severe (9.94%) with $p = 0.0006$, higher material cost with $p = 0.0018$, the occurrence of vomiting (10.56%), delayed awakening (22.36%), pain after MVA (21.74%), and a weak change in the modified Abortion score at 30 minutes post-MVA (70.19%) in relation to RAS (81.61%) $p = 0.0002$.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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