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Original Research Article

# Comparison of ketofol versus propofol for procedural sedation and analgesia in cervical cancer brachytherapy: A prospective, randomized double blind study

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ABSTRACT

**Introduction:** Most common drug used for outpatient procedural sedation and analgesia is propofol, with limitations like systemic hypotension. Combining propofol with ketamine preserves sedation efficacy, minimizing their respective adverse effects. So, we aimed to compare ketofol (ketamine+propofol) versus propofol regarding their total drug consumption, recovery profile, effect on haemodynamic and respiratory parameters in brachytherapy patients.

**Materials and Methods:** A prospective, randomized, controlled double blind study was carried out in 100 female patients between 20-60 years, 30-70kg, ASA I-III undergoing brachytherapy as outpatient procedure on elective basis, after ethical clearance from institutional committee. These were randomly divided into 2 groups (50 each). Group P-Injpropofol (10mg/ml) 2mg/kg for induction and 20mg as supplementation. Group K-Injketofol (10mg/ml) (ketamine 50mg+propofol 100mg, 1:2) 2mg/kg for induction and 20 mg as supplementation.

**Results:** The supplementation dose required was significantly higher in propofol group (800mg) as compared to ketofol group (20mg) (p=0.00). Also, the fall in SBP and DBP was significantly less in ketofol group than propofol group (p<0.01). The mean awakening time (time from end of procedure to MRSS =3) andmean recovery time (time from end of procedure to achievement of Aldrete score 10) was more in ketofol group than propofol group (p<0.003), the difference was less than 1-2 min, so it was clinically not significant.

**Conclusion:** Ketamine-propofol combination in 1:2 ratio in a single syringe as ketofolis better alternative to propofol in providing sedation and analgesia with better haemodynamic stability, for outpatient brachytherapy procedure in cancer cervix patients.



## 1. Introduction

Cervical cancer is the third-most common cancer among women worldwide. In the developing world, it is the second leading cause of cancer death among women.[1] For women who develop locally advanced cervical cancer, the standard of care has evolved from external beam radiation therapy (EBRT) alone, to EBRT plus brachytherapy, to combined EBRT plus brachytherapy with concurrent chemotherapy.[2]

Brachytherapy for cervical cancer can be performed using an Intracavitary approach, Interstitial approach or combination approach in which interstitial catheters are placed in combination with a Intracavitary applicator.[3] Brachytherapy is a short outpatient procedure which requires procedural sedation and analgesia (PSA). Goals of PSA include providing an adequate level of sedation while minimizing pain and anxiety, maximizing amnesia, minimizing the potential for adverse drug-related events and maintaining a stable cardiovascular and respiratory status. Unfortunately, at this time no single agent exists that has all of the aforementioned qualities. Thus, combination of different drugs has to be used in varying doses to achieve as many of the desired goals as possible. Propofol is a non-barbiturate sedative hypnotic with quick onset and

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short recovery time also having antiemetic, anticonvulsant and amnestic properties. Although extremely effective and potent, propofol use is limited by a relatively high incidence of dose dependant hypotension and respiratory depression. Still, Propofol remains the most commonly used anesthetic agent for outpatient anesthesia.[4,5]

Ketofol is a combination of Ketamine and propofol in a single syringe and can be prepared in any desired concentration. Ketamine and propofol are physically compatible for 1 h at 23°C and have been combined in different proportions (1:1 to 1:4) for different surgical procedures.[6–10] It is postulated that combining these two agents for PSA may preserve sedation efficacy while minimizing their respective adverse effects. This is due partly to the fact that many of the aforementioned potential adverse effects are dose-dependent, and when used in combination the doses administered of each can be reduced.[11] Also, the cardiovascular effects of ketamine and propofol are opposing in action, thus theoretically balancing each other out when used together. Though ketofol is a relatively new idea for most practitioners, various studies[8–13] have demonstrated that combination of ketamine and propofol (ketofol) for procedural sedation and analgesia (PSA) is safe and effective. Ketofol versus propofol have been compared in various procedures (like tubal sterilization,[13] Dilatation and curettage,[14] ERCP,[15] burn dressing[16] etc. but for brachytherapy it is yet not studied.

We aimed to compare two agents ketofol versus propofol in outpatient anaesthesia for cervical brachytherapy regarding their sedo-analgesia effects, total drug consumption, recovery profile, effect on hemodynamic and respiratory parameters and adverse events etc. Our ultimate objective was to evaluate whether ketofol offers any advantages over propofol which is the most common agent used for outpatient anaesthesia in brachytherapy patients.

## 2. Materials and Methods

After taking approval from institutional ethical committee, this prospective, randomized, double blind study was carried out in 100 female patients undergoing brachytherapy for carcinoma cervix in Department of anaesthesia in brachytherapy OT in MB Govt. hospital, RNT medical college, Udaipur (Raj). A written informed consent for procedural sedation and analgesia (PSA) for brachyterapy and to participate in the study was taken.100 female patients between 20-60 yr old, weighing 30-70kg with ASA grade I, II, III, undergoing brachytherapy in PSA as outpatient procedure on elective basis, who fulfill the study criteria were enrolled for the study. Patient with acute or chronic hepatic disease, renal disease, cardiovascular disease, central nervous system disease, psychiatric illness, alcohol or substance addiction, endocrine disorder or any other systemic disease, hypersensitivity to drugs planned to be used in the study and patients who refused were excluded from the study.

### 2.1. Basis of sample size

Sample size was calculated on the basis of previous study by Akin A et al (2005)[17] in which repeat dose of medication was needed in 70% patients in propofol group and 26.66% in ketofol group. For present study, to detect the similar difference in need of repeat dose of medication in two groups (propofol versus Ketofol), a minimum sample size of 48 in each group is required at a power of 80% and confidence interval 95%. We took 50 patients in each group i.e total 100 patients to compensate for dropouts.

### 2.2. Randomization and group allocation

100 selected study patients were randomized into two groups of 50 each using a computer generated table of random numbers kept in opaque sealed envelopes. Group P (Propofol group), n=50: received inj. Propofol (10 mg/ml) in dose of 2 mg/kg for induction and 20 mg increments for supplementation when required. Group K (ketofol group), n=50: received inj. Ketofol (10mg/ml) in dose of 2 mg/kg for induction and 20 mg incremental does for supplementation if needed.

Drug preparation: Group P (Propofol group): 15 ml (150 mg) of inj. Propofol was taken in 20 cc syringe. Total drug is 150 mg propofol and drug concentration is 10 mg/ml of propofol.

Groups K (Ketofol group): 1 ml (50 mg) inj. Ketamine +10 ml (100 mg) inj. Propofol +4 ml 5% dextrose making volume of 15 ml was taken in 20 cc syringe. Total drug is 150 mg of ketofol and drug concentration is 10 mg/ml of ketofol. Each ml of ketofol contains 3.33 mg Ketamine and propofol 6.66 mg, making 1:2 ratio of Ketamine and propofol.

### 2.3. Procedural sedation and analgesia (PSA) technique

After a thorough preanesthetic evaluation, Patient were kept fasting overnight. In pre-induction room, a peripheral i.v. cannula of 20G was taken in arm and inj. Ringer lactate 500 ml was given. After shifting to brachyterapy OT room, patient was monitored for baseline vital parameters like noninvasive blood pressure (NIBP), pulse oximetry ($SpO_2$), ECG, heart rate (HR) and respiratory rate (RR).

Patient received intravenous premedication with inj. glycopyrolate 0.2 mg, midazolam 1 mg, fentanyl 1 mcg/kg. After 3 min, SBP, DBP, HR, RR, $SpO_2$ were recorded and considered as baseline value for further data recording. Patient was induced with 2 mg/kg of propofol (Group P) or ketofol (Group K) as per group allocation, given over 60 sec.

Sedation-analgesia was assessed using modified Ramsay sedation score (MRSS, 0-6)[18] as follows: 0- Paralyzed, unable to evaluate, 1- Awake, 2- Lightly sedated, 3- Moderately sedated, follows simple commands, 4- Deeply sedated, responds to non-painful stimuli, 5- Deeply sedated responds only to painful stimuli, 6- Deeply sedated, unresponsive to painful stimuli.

Target sedation for procedure was achievement of MRSS score 6 (no response to pain). MRSS was assessed every 5 min till completion of procedure. Whenever MRSS came below 6 (response to pain starts), repeat dose of 20mg of same drug was given. Amount of additional doses and timing of supplementation were recorded.

Throughout procedure, patient was oxygenated using 100% oxygen via Bain's circuit on spontaneous ventilation. Respiratory depression (defined as apnea, respiratory rate <8/min, SPO2 <90%) was treated with mask ventilation with 100% O2 using Bain's circuit, and if needed, patient was intubated. If SBP falls below 20% baseline or SBP <90 mmHg, it was considered as hypotension and treated with IV fluid and inj. Mephentermine 6 mg intravenous. If HR falls below 55 beat/min, it was considered as bradycardia and inj. atropine 0.4mg IV was given. Duration of procedure was recorded. Criteria to allow shifting of patient to recovery room were achievement of MRSS 3 or less. MRSS was assessed at the end of procedure and thereafter every 1 min till MRSS of 3 is achieved. If patient and surgeon had any complaint in perioperative period, that were noted and treated accordingly. Modified Aldrete score[19] (0-10), was noted at the end of procedure, and 5 min thereafter, till achievement of Aldrete score of 10; which was criteria to shift the patient to postoperative ward.

Patients were also assessed at 30min, 1hr, 2hr, 3hr, and 4hr postoperatively in ward for any adverse effect like hallucination, nausea, vomiting, headache, etc. When patient complained of pain postoperatively, time was noted (defined as duration of analgesia). Diclofenac 75 mg IV was given as rescue analgesic as per hospital protocol. Patients were discharged after 6 hour on the same day. If any complication occurred, then patient were admitted overnight and treated accordingly.

### *2.4. Data recording*

Parameters like age, sex, weight, stage of cervical cancer and details of brachytherapy were noted. Start of induction agent was taken as time zero for all data recording. MRSS (0-6) was recorded immediately after induction, every 5 min throughout the procedure, and at the end of surgery and at every 1 min postoperatively till achievement of MRSS=3 to know awakening time. Time of intra-operative pain, need for repeat dose, and total dose of sedating agent were noted. Awakening time was time from the end of procedure to MRSS 3. Recovery time was time from end of procedure to achievement of aldrete score of 10. SBP, DBP, HR, $SpO_2$, RR were assessed at shifting to OT table, after premedication (before induction), just after induction, at 3min, 5min and thereafter every 5 min intra-operatively, at the end of procedure, postoperatively every 5 min, till Aldrete score 10. Incidence of hypotension, bradycardia, nausea, vomiting, headache, hallucination or any other side effects, if occur, were noted and treated accordingly. Time of discharge of patient was also noted. If patient and surgeon had any complaint in perioperative period, that were noted.

### *2.5. Statistical analysis*

Data was analyzed using SPSS Version 20. Categorical data were presented as a number (percentage) and compared with chi-square test. Continuous variable were presented as mean ± SD and compared with t- test. P<0.05 was considered as statistically significant.

## 3. Results

1. Baseline characteristics.
2. Both groups were comparable regarding age, weight, ASA grade, FIGO staging, duration of procedure, baseline investigations and baseline hemodynamic parameters of patients, p>0.05. (Table 1)
3. Consumption of propofol and ketofol in two groups-
4. Mean induction dose of ketofol in group K was 94.48±15.94 mg and propofol in group P was 95.80±18.30 mg which was comparable, P=0.701. 26(52%) patients in group P required total 40 supplementation doses of propofol (800mg total) while in group K only 1(2%) patient required 1 supplement doses of ketofol (20 mg). The difference in supplementation dose consumption was highly significant in two groups (P=0.000), (Table 2).
5. Haemodynamic profile.
6. Mean SBP and Mean DBP were significantly lower in Group P as compared to Group K just after induction, at 3 min, 5 min and 10 min (P=0.000) (Figures 1 and 2). Thereafter they were comparable in two groups throughout the procedure, P>0.05. As compared to baseline, maximum fall in SBP was 26.08 mmHg (19.84%) in group P and 7.68 mmHg (5.92%) in group K. Similarly, maximum fall in DBP was 8.94mmHg (10.85%) in group P, while in group K, DBP showed a fall of only 0.82mmHg (1.01%) from baseline. Thus, blood pressure was better maintained in group K as compared to Group P. However, in Group P, fall in SBP and DBP was well within 20% of baseline. And none of the patient had fall in SBP <90mmHg, and DBP <50mmHg. So, none had hypotension and hence did not require any vasopressor treatment. Mean pulse rate was comparable in two groups at all time intervals, P>0.05, (Figure 3).
7. Recovery characteristics.

8. Awakening time (Time to RSS=3) in group P (1.66±1.30min) was significantly shorter as compared to group K (2.82±1.33min) P=0.00. However, the difference was around 1min (1.16min) that could not make much clinical significance (Figure 4). Recovery time (Time to Aldrete score 10) in group P (4.74±2.56min) was also significantly shorter as compared to group K (6.50±3.27min) P=0.003. However, the difference was < 2 min (1.76) hence could not make much clinical significance (Figure 5).
9. Complications.
10. None of the patient in any of the group had complication like hypotension, bradycardia, respiratory depression, nausea, vomiting, hallucination etc. Radiotherapist did not complain in any case regarding anesthetic condition of patient. All patients in both groups had good outcome and all were discharged on same day uneventfully.

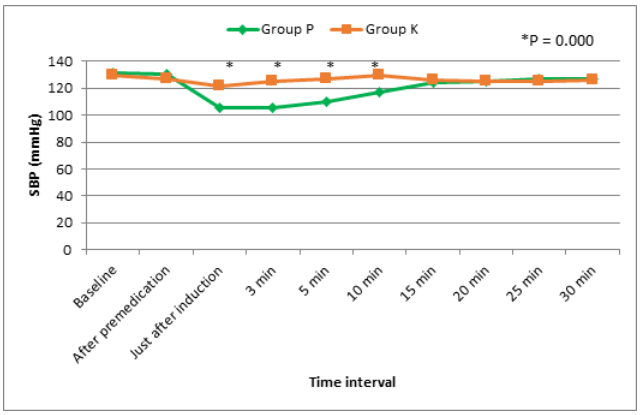


**Fig. 1:** Comparison of mean systolic blood pressure (SBP) in two groups

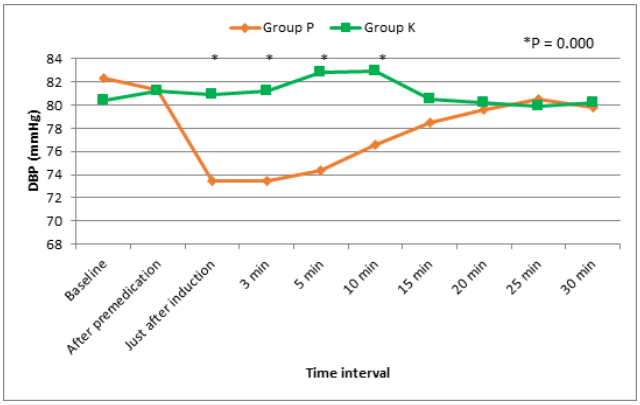


**Fig. 2:** Comparison of diastolic blood pressure (DBP) in two groups

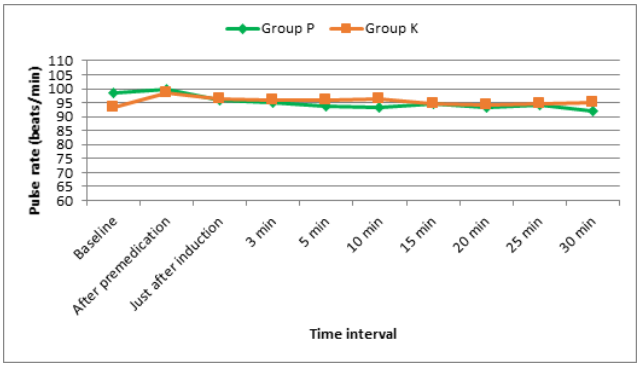


**Fig. 3:** Comparison of pulse rate in two groups

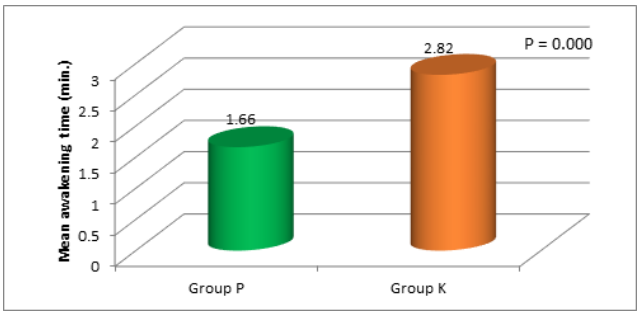


**Fig. 4:** Comparison of mean awakening in two groups

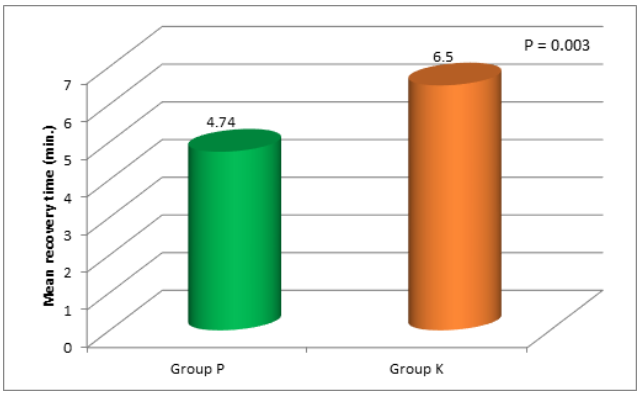


**Fig. 5:** Comparison of recovery time in two groups

## 4. Discussion

In present study we compared ketofol and propofol to provide procedural sedation and analgesia for cervical cancer brachytherapy performed as outpatient procedure. We found that in Group K, total consumption of Ketofol was significantly less (94.9 ± 16.07 mg) as compared to propofol consumption (111.8 ± 26.16 mg) in Group P, p= 0.000. Induction dose of ketofol (94.48±15.9 mg) and propofol (95.8±18.30 mg) were comparable, p= 0.701, however, intraoperative supplemental dose requirement was significantly higher in Propofol group [26(52%) patient required total 40 doses (800 mg) in Group P] as compared

**Table 1:** Comparison of demographic parameters between two groups

| Parameter | Group P (n=50) | Group K (n=50) | P value |
|---|---|---|---|
| Age (years) | 51.96±10.46 | 51.52±8.91 | 0.821 |
| Weight (kg) | 47.9±9.09 | 47.22±7.94 | 0.691 |
| Sex- Female | 50 (100%) | 50 (100%) | - |
| Procedure time (min.) | 13.50±4.36 | 13.36±3.97 | 0.867 |
| Hb (gm/dl) | 9.8±0.76 | 10.09±0.78 | 0.063 |
| Platelet count (lakh/$mm^3$) | 2.05±0.63 | 1.99±0.57 | 0.610 |

**Table 2:** Comparison of consumption of propofol and ketofol in two groups

| | Group P (n=50) | Group K (n=50) | P value |
|---|---|---|---|
| Induction dose (mg) | 95.80±18.30 | 94.48±15.94 | 0.701 |
| No. of patients who required Supplementation | | | |
| n(%) | 26 (52%) | 1 (2%) | |
| 1 dose | 15 (30%) | 1 | |
| 2 dose | 9 (18%) | 0 | |
| 3 dose | 1 (2%) | 0 | |
| 4 dose | 1 (2%) | 0 | |
| Total no. of supplementary doses (dose in mg) | 40 (800 mg Propofol) | 1 (20 mg Ketofol) | 0.000 |

to only 1(2%) patient required single dose (20 mg) ketofol in Group K, p=0.000.

Our findings were in coherence to previous studies. Isik et al reported that 66.6% patients in propofol group required additional dose of propofol as compared to none in ketofol group. Akin et al. reported that 21 out of 30 patients of propofol group required supplemental dose as compared to 8 out of 30 patients in ketofol group. Propofol consumption was significantly higher as compared to ketofol group in studies by Hasanein et al. [97.08±23.31 mg vs 57.7±6.79 mg, p<0.01], and Ariken et al. [135.65±40.2 mg vs 91.42 ±23.7 mg, p<0.05] respectively.

Kurdi et al compared three groups: as Group A (Ketamine: Propofol 1:1), Group B (Ketamine: Propofol 1:2) and Group C (Propofol: Fentanyl). Propofol consumption was highest in Group C (1.89±0.18 mg/kg) than in Group B (1.74±0.19 mg) and least in Group A (1.60±0.30 mg/kg). The difference was significant between Group A and Group C, p=0.014. Propofol consumption was in order of Group A< Group B< Group C.

Above studies including ours show that the addition of small dose of ketamine to propofol provides an analgesic component and decreases the total dose of propofol needed for the same level of sedation. Propofol produce sedation by action on GABA receptor,[20,21] while ketamine is an NMDA receptor antagonist, it also binds to opioid receptors and sigma receptors, causing "dissociative anesthesia."[20,22] Hence additional supplementation requirement and total anaesthetic consumption are reduced in ketofol groups. It suggests synergism between ketamine and propofol.

We also observed that haemodynamics were better maintained in ketofol group as compared to propofol group. Previous studies[7,13,14] also demonstrated that the combination of propofol and ketamine in ketofol provides a more stable hemodynamic profile than propofol used individually. The hypotensive effect of propofol is related to the impairment of the baro-reflex mechanism and sympathetic inhibition[20,21] while Ketamine stimulates cardiovascular system and increases the HR, BP and systemic vascular resistance.[20,22] More importantly, these cardiovascular system effects are dose dependent which may increase with an increased dose of both agents. Ketofol is combination of ketamine and propofol in single syringe as they are physically compatible. Cardiovascular effect of ketamine and propofol are opposing in action, thus balance each other out when used together. That's why ketofol produces more stable hemodynamic and respiratory profile as compare to when either agent is used alone.

In present study because of addition of ketamine, awakening time (Time to MRSS3) and recovery time (Time to Aldrete 10) since end of surgery were slightly longer in ketofol group as compared to propofol group, but the difference was 1-2 min that did not make much clinical significance. Previous studies[7,14,15] including ours show that awakening time and time to discharge from preanesthetic care unit in the ketofol group were within acceptable range. However, they were slightly longer in ketofol group than in group fentanyl-propofol. Slower clearance of ketamine in comparison to fentanyl is probably responsible for this. Ketamine is NMDA receptor antagonist and produces dissociative anesethesia. While propofol is GABA receptor antagonist and preferable agent for outpatient anesthesia because of its early recovery profile due to their small volume of distribution.[20] However, when small subanaesthetic doses of ketamine are added to propofol in ketofol does not cause much prolonged sedation

as compared to when ketamine was used alone. Recovery time is adversely affected when proportion of ketamine increases in ketofol (1:1 to 1:5). Increased discharge times were found when high proportion of ketamine was used in ketofol. Recovery time was in order of Group C> Group A> Group B. In Group C, supplemental dose of propofol was very high so sedation as longest among three groups. In Group B, Ketamine: Propofol were used in 1:2 ratio and caused better recovery profile as compared to Group A where ratio was 1:1.

In present study none of the patient in any of the group had complication like hypotension, bradycardia, respiratory depression, nausea, vomiting, hallucination etc. It was noteworthy that in ketofol group, no patient had hallucination, it could be because we used small dose of ketamine (0.5mg/kg), and midazolam and fentanyl were used in premedication. Outcome was good (uneventful) in all patients in both groups.

In previous studies also adverse effects were minimal and comparable in two groups. Hypotension, bradycardia, tongue fall, apnoea were seen in propofol group while tachycardia, increased secretions, nausea, vomiting, hallucination were seen in ketofol group.

The limitation of our study was that we could not assess level of sedation and analgesia by using sophisticated monitors like bispectral index and electroencephalography due to their non-availability. We measured it only by modified Ramsay sedation score which is a subjective method and less reliable measure as compared to above mentioned objective methods.

## 5. Conclusion

We conclude that Ketamine-propofol combination in 1:2 ratio in a single syringe as ketofol is found as a better alternative to propofol in providing sedation and analgesia for outpatient brachytherapy procedure in carcinoma cervix patients ; because use of ketofol was associated with better haemodynamic stability and lesser need for repeat supplementary doses. Although, recovery with ketofol is little delayed as compared to propofol but the difference was of 1-2 min that did not make much clinical difference.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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