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PROPOFOL VS. THIOPENTAL NA;
PREGNANCY OUTCOME AND POSTOPERATIVE NAUSEA AND VOMITING (PONV) IN ART CYCLE

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ABSTRACT: Objective: The aim of this study was to compare the side effects, fertilization rate and pregnancy rate (PR) and duration of recovery between Propofol and Thiopental Na after ICSI-vaginal retrieval of oocyte in ART cycle. **Design:** This study was a prospective, randomized clinical trial Materials and **Methods:** Ninety eight ASA(American Society of Anesthesiologist) physical status I and II women participating in an intracytoplasmic sperm injection(ICSI) program were assessed. All of the patients underwent general anesthesia induction with Propofol and Thiopental Na. The first group (49cycles) received 2-2.5mg/kg of Propofol, and the second group (49cycles) received 5mg/kg Thiopental during transvaginal oocyte retrieval. An informed consent form was obtained for each patient's treatment. Variables under study included: female age, cause and duration of infertility,postoperative nausea and vomiting(PONV), heamodynamic changes, mean number of oocyte retrieved, oocyte metaphase II, embryo cleaved, embryo transferred, embryo quality and pregnancy rate(PR)and duration recovery. Statistical analysis was carried out by using SPSS.10 software and statistical test of T-test and chi-square. **Results:** The PR in Propofol group was 18(36.7%) and in Thiopental Na group was 19(38.8%) with no significant differences the mean duration of infertility and weight weren't statistically significant. The mean number of oocyte retrieved (metaphase II), embryo cleaved, embryo transferred and embryo quality weren't significant between the two groups. The incidence of nausea in Propofol group in comparison with Thiopental Na group was lower with significant differences. The incidence of vomiting between two groups was statistically significant (46.9% vs.28.6% respectively)(P<0.05). between two groups. Duration of recovery in Propofol group was 15+/_3min and in Thiopental Na group was 25+/_5 min that was statistically significant(P<0.05). **Conclusions:** Propofol offered lower incidence of post operative nausea and vomiting and a quick recovery from anesthesia without any adverse effect on pregnancy outcome. These findings showed that Propofol was a good alternative for Thiopental Na in short time operation, like ICSI -vaginal retrieval of oocytes.

Keywords: Propofol, thiopental Na, Intracytoplasmic sperm injection (ICSI),vomiting, nausea, embryo transfer, fertilization rate, Pregnancy rate (PR).

INTRODUCTION

Transvaginal ultrasonography guided oocyte retrieval (TVOR) is commonly performed as part of in vitro fertilization (IVF) efforts. This procedure is carried out

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under general, regional or local anesthesia[1].

General anesthesia especially total intravenous anesthesia (TIVA) is an appropriate method for TVOR. The impact of anesthetic management on patient outcome from this procedure has not been well characterized[2] but Propofol and Thiopental Na are two agent that frequently used for TIVA.

Thiopental Na is an old and popular Thiobarbiturate with excellent hypnotic effects. It induced prompt onset anesthesia, smooth induction and rapid emergence. Propofol, one of a group of alkylphenols, is the most frequently used anesthetic today, because of its fast onset, short effect duration, antiemetic effect and post operative well-being[3].The use of Propofol as compared to Thiopental Na for short surgical procedures has been associated with more rapid recovery from the anesthesia[4]. There are controversial reports with regard to the influence of Propofol anesthesia on implantation rates and clinical pregnancy rates in humans[5,7].

Several authors found no detrimental effects or negative outcome in human or animal during IVF when Propofol was used[8].The most common complication in post anesthetic care unit (PACU) is nausea and vomiting[9,11]particularly in out patients, because they can delay discharge and may result in unplanned overnight hospital admission[12,15]. PONV can induce patient discomfort and pulmonary aspiration. Some of risk factors for PONV that including patients scheduled for TVOR under GA are: younger age, female gender, anxiety, general versus regional or local anesthesia, type of surgery (ovum retrieval).

We can prevent PONV by antiemetic drugs like metaclopramide[16] and droperidol[9,15].But both of them have been known to induce hyperprolactinemia, which has subsequently impaired ovarian follicle maturation and corpus luteum function in women[3].The likelihood of emesis increases with ART stimulation owing to the changes in plasma esteradiol levels, patients undergoing IVF with estrogen levels that increased less than 10-fold and more the 10-fold, experienced 26% and 39% incidence of emesis, respectively[9].

Therefore the aim of this study was comparison of fertilization rate, embryo quality, pregnancy rate , PONV, hemodynamic stability and duration of recovery between two groups that anesthetized with Propofol or Thiopental Na after ICSI-vaginal retrieval of oocyte.

MATERIALS AND METHODS

This study was a prospective, randomized clinical trial. The study group included infertile women scheduled for oocyte retrieval. Ninety eight consecutive cycles of ultrasound-guided transvaginal oocyte retrieval (TVOR) at the Mehr Infertility institute were chosen. The patients underwent ICSI because of female, male, both or unexplained factors. Written informed consent was obtained from all patients.

All patients were American Society of Anesthesiologist (ASA) physical status I or II. Patients were excluded if they had history of vomiting disorders, motion sickness, drug allergy, hypotension (Bp<90/60), hypertension (Bp>140/90), diabetes Mellitus, chronic cholecyctitis, neuropathy or neuromuscular disorders that could produce delayed gastric emptying.

Blood pressure (Bp) were measured in supine position for two times with 15 minutes interval during preoperative visit. When the mean of Bp didn't report 20% lower of baseline, they included in this study.

Using a random -number table, patients were randomly allocated to two groups, Propofol (P) group and Thiopental Na(T) group(n=49 in each group).

Technique of anesthesia was total intravenous anesthesia (TIVA) patients received premedication with midazolam 1 mg and fentanyl 2mcg/Kg, 5minutes before induction and prehydrayted with 3ml/kg Ringer solution. In Propofol group induction of anesthesia was done with Propofol 2mg/Kg and in Thiopental group with Thiopental 5mg/Kg.

Anesthesia maintenance was carried out with assisted mask ventilation with O2.When complementary doses were required 20% of the initial dose of induction drug was administered. Because of brief duration of these

procedures, about 15 – 30 minutes, total dose of drugs in (P) group was up to 3 mg/kg propofol and in (T) group up to 7 mg/kg Thiopental Na. The type and volume of intravenous serum was Ringer 500 cc and 1/3,2/3 500 cc during anesthesia and recovery. Oocyte retrieval was performed transvaginally as previously described [17].

When retrieved adequate sperm for starting of the ICSI procedure, the ICSI was performed on all normal MII stage(second metaphase)oocytes. Fertilization assessment was performed,16-18 hours later by observation of two pronuclei (2pn).48 to 72 hours after ICSI if any normal cleaved embryos were available embryo transfer(ET) was performed. All patients were evaluated for Hemodynamic derangements, nausea and vomiting for the first hour in the post anesthesia care unit and there after in the post operative ward for 3hrs later by a person who was blinded to the study.

The Hemodynamic end-points of anesthetic management were the maintenance of BP and HR to within 20% of pre-induction values. Hypotension was treated with intravenous ephedrine 5-10mg .Nausea was defined as a subjective, unpleasant sensation in the epigastrium and the throat with the urge to vomit. Vomiting was defined as the forceful expulsion of gastric contents from the mouth. Retching was defined as the labored contraction of diaphragm and abdominal muscles without any expulsion of gastric contents.

Metoclopramide 0.1mg/Kg IV was given as a rescue antiemetic if more than 3 emetic episodes prevailed. Every complications or side effects of drugs in two groups were studied. Recovery time from end of operation to full patient awareness on time and place and ability to move herself from operation table to PACU Stretcher and from PACU stretcher to ward stretcher without any hemodynamic instability was measured in two groups.

At our institution, every patient undergoing anesthesia for ART(Assistant Reproductive Techniques)receives a follow up call at 24 hours post procedure to assess for questions or complications.

STATISTICAL ANALYSIS

The clinical pregnancy rate (PR) was verified by the presence of gestational sac on the 6th week of pregnancy with vaginal sonography. The PR was evaluated with female age, male age, cause and duration of infertility, PONV, hemodynamic changes, mean number of oocyte retrieval ,oocyte metaphase II, embryo cleaved ,embryo cleaved transferred ,embryo quality and recovery time by using chi-square test , T-Test and Mann Whiteny test. In an effort to establish the factors associated with the success of ICSI, multivariate analysis was performed based on logistic regression.

RESULTS

Totally the mean age of females and duration of infertility were 31.3± 5.5 and 9.8±6.6 years respectively. The mean age of female was significantly different in the Propofol and Thiopental Na group (30.1±5.1 and 32.7±5.5 years respectively) ($P<0.05$).Data showed that mean duration of infertility and the mean of weight weren't significantly different between two groups($p>0.05$). Recovery time was 25±5 minutes in Thiopental Na group and 15±3minutes in Propofol groups that had statistically significant difference ($P<0.05$) (Table-I).

Table-I. Patients characteristics in the Propofol and Thiopental Na groups.			
Variable	**Thiopental Na Mean±SD**	**Propofol Mean±SD**	**T-Test**
Female age (y)	30.1±5.1	32.7±5.7	P<0.05 s
Male age (y)	35.2±6.4	34.9±5.3	P>0.05
Duration of infertility	7.7±4.8	6.8±4.2	P>0.05
Weight (kg)	73.3±15	69.1±13.7	P>0.05
Serum usage	1.4±0.2	1.3±0.2	P>0.05
Recovery duration (min)	25±5	15±3	P<0.05

Totally 934 oocyte was retrieved that 703(75.2%) mature oocytes were injected. Cleavage rates was 553(78.6%) respectively also the number of embryo transferred and embryo implantation was 280(50.6%) and 47(16.7%) respectively.

The mean number of oocyte retrieval (MII), embryo cleaved, embryo transferred hadn't statistically significant effect on PR between two groups (P>0.04)(Table-II).

Table-II. Oocyte and embryo characteristics in the Propofol and Thiopental Na groups.			
Variable	**Thiopental Na Mean±SD**	**Propofol Mean±SD**	**Mann-Whiteny Test**
Oocyte retrieved	9.5±7.2	9±5.3	P>0.05
Oocyte injected (MII)	8±4.9	6±4.2	P>0.05
Cleaved embryos	3±0.8	5±2.9	P>0.05
Embryos transferred	3±1.5	3±0.8	P>0.05

Results indicated that categories of infertility and embryo quality weren't statistically significant between two groups (P>0.05).

Overall PR was 37.8% that PR in Propofol was18 (36.7%) and in Thiopental Na group was 19(38.8%) that there wasn't any significant difference between two groups (P<0.05).

Incidence rate of nausea in Propofol group was lower than in Thiopental Na group 17(34.7%) vs.25(51%) that was statistically significant(P<0.05).

There was reduction in incidence rate of vomiting in the Propofol group compared to the Thiopental Na group: 14(28.6%) vs.23(46.9%)(P<0.05).

The relative number of emetic episodes and the need for rescue antiemetic therapy was also reduced in Propofol group. Metoclopramide were given to 6(12.2%) of the patients in the Thiopental Na group while 1 case (2%) in the Propofol group required the same (P<0.05)(Table3).

Hemodynamic changes (blood pressure and heart rare), amount of crystalloid solution consuming and drug treatment in Propofol group were not significantly different compared with Thiopental Na(P>o.o5). Multiple logistic regressions showed no significant effect of female age, male age, cause and duration of infertility, PONV, hemodynamic changes, mean number of oocyte retrieval ,oocyte metaphase II, embryo cleaved ,embryo cleaved transferred and embryo quality in the outcome of IVF/ICSI (P>0.05).

Table-III. Comparison of infertility causes, PONV, embryo quality in the Propofol and Thiopental Na groups.		
Variable	**Thiopental Na (%)**	**Propofol (%)**
Cause		
Female factor	14 (28.6)	17 (34.7)
Male factor	20 (40.8)	18 (36.7)
Unexplained	4 (8.2)	8 (16.3)
Male and female	11 (22.4)	6 (12.2)
*** Nausea**		
Yes	25 (51)	17 (34.7)
No	24 (49)	32 (65.3)
*** Vomiting**		
Yes	23 (46.7)	14 (28.6)
No	26 (53.1)	35 (71.4)
*** Metaclopramide**		
Yes	6 (12.2)	1 (2)
No	43 (87.7)	48 (97.9)
Pregnancy Rate		
Yes	19 (38.8)	18 (36.7)
No	30 (61.2)	31 (63.3)
Embryo quality		
A	42 (85.7)	42 (85.7)
B	7 (14.3)	6 (12.2)
C	---	1 (2)

DISCUSSION

This study compared PONV and pregnancy outcome in patients who were treated by ICSI after transvaginal oocyte retrieval under general anesthesia with Propofol or Thiopental sodium.

The two groups of patients were well matched according to the demographic and clinical data. PONV are unpleasant, often underestimated side effects of anesthesia and surgery, not devoid of medical complications. Prevention with antiemethics is only partially effective. Number of prospective randomized comparative studies has suggested that there is a reduction in PONV following maintenance of anesthesia with Propofol compared with inhalational agents[17,22].

In our study there was reduction in incidence rate of vomiting in the Propofol group when compared to the Thiopental Na group:14(28.6%)vs.23(46.9%)(P<0.05), here statistically significant difference in nausea incidence between two groups was shown: 17(34.7%) vs. 25(51%)(P<0.05),also antiemetic therapy was reduced in Propofol group compared with Thiopental group (2% vs.12.2%)(P<0/05)

Myles have analyzed data on 4173 patients using multivariate logistic regression, with an overall incidence of PONV 21.3% .Propofol ,when compared to Thiopental for induction of 1996 anesthesia, resulted in 18% reduction in PONV (P<0.05)[23].

Klockgether-Radke et al compared PONV and recovery scores with Propofol and Thiopental/halothane anesthesia. The overall incidence of emetic sequelae (nausea or vomiting was 43% in group Thiopental and 23%, in group Propofol (P>0.05). Patients with Propofol anesthesia had lower emetic scores and higher recovery scores compared with those after Thiopental/halothane anesthesia[24].

In present study hemodynamic changes (BP and HR) were not significantly different between Propofol group and Thiopental Na group (P>0.05)

Hassani et al evaluated the effect of Propofol and Thiopental Na on blood pressure and heart rate during induction in elective surgery. Propofol induction produced more stable hemodynamics after intubation in patients than did Thiopental Na induction. Therefore, it is suggested to use Propofol for induction and intubation in patients[25].

Alijanpour et al compared hemodynamic variations in induction of anesthesia and PONV with Propofol and Thiopental Na. Data showed that the variation of heart rate with Propofol after induction of anesthesia and intubation was minimum but ,it increased with Thiopental

Na and this difference was considered significant (P<0.05). PONV between two groups was not statistically meaningful[3].

According to the results, Propofol better than Thiopental Na prevents from hemodynamic response due to intubation. So, Propofol can be used instead of Thiopental Na in patients that Thiopental Na is contraindicated, or in those whose minimum increase of blood pressure is acceptable during intubation[3].

Therefore results about PONV in our study matched with Myles and Klockgether - Radke studies. But in Alijanpour study PONV between two groups was not statistically meaningful that was different with ours , maybe due to difference in type of surgery and need for endotracheal intubation in Alijanpour study

General anesthesia with IV agents seems to be the most popular form of pain control for transvaginal oocyte retrieval in assisted reproduction[17].

Concern has been expressed as to possible detrimental effects of anesthetic and analgesic agents on the results of assisted reproduction treatments.

In our study the mean number of oocyte retrieval (MII), embryo cleaved, embryo transferred and embryo quality weren't significantly different between Propofol group and Thiopental Na group (P>0.05)

Vincent et al in an evaluation of the effect of anesthetic technique on reproductive success after laparoscopic pronuclear stage transfer investigated that propofol anesthesia for laparoscopic pronuclear stage transfer is associated with lower clinical and ongoing pregnancy rates compared with isoflurane[30].

Christians et al compared fertilization rates and embryo development and the implications for reproductive outcome and pregnancy following general anesthesia with Propofol or paracervical local anesthesia block during TVOR in patients undergoing fertility treatment. There were no differences between the fertilization rates and the embryo cleaved characteristics for the two groups[26].

Rosenblatt et al investigated the effect of a Propofol-based sedation technique on cumulative embryo scores, clinical pregnancy rates and implantation rates in patients undergoing embryo transfers with donor oocytes. There was no evidence from their data that the administration of Propofol during the aspiration of ovarian follicles for oocyte donation had a negative impact on the oocytes as measured by cumulative embryo scores, probability of a clinical pregnancy, or implantation rate[7].

Pierce et al compared pregnancy rate following gamete intrafallopian transfer (GIFT) under general anesthesia with Thiopental Na or Propofol .Clinical pregnancy following each GIFT procedure was assessed by multiple –serum beta human gonadotropins and ultrasound determinations. The pregnancy rates of 24.6% and 25.8% for the Thiopental and Propofol groups, respectively, were not significantly different[14].

Huang et al in a retrospective study compared effects of Propofol and Thiopental Na if they were used for induction of anesthesia for TVOR on outcome of ART. They found no significant differences between these two drugs for fertilization rate, cleavage rate, pregnancy rate, implantation rate and abortion rate[8].

Soltani Mohhamadi et al compared pregnancy outcome and duration of recovery under general anesthesia with Propofol and Thiopental Na for TVOR .They found no significant differences between two groups for fertilization rate and pregnancy rate but Propofol group had more rapid post operative recovery than Thiopental group(22.1+/-6.2 min vs38.6+/-3.9min)[27].

Chittleborough et al in a double –blind study compared patient's recovery after induction with Propofol or Thiopental Na for day-case relaxant general anesthesia in 40 ASA 1 un premeditated day surgery patients. Mean recovery times in the Propofol group ,required for patients to sit out of bed and meet discharge criteria(44.8 and113.1minutes,respectively)were significantly (P<0.05) shorter than those in the thiopentone group(59.7 and 133.5 minutes, respectively) fewer patients in the Propofol group were treated in the recovery room for nausea and vomiting[28].

Huang et al investigated effects of induction anesthetic agents on outcome of assisted reproductive technology. They found that induction with Propofol as compared to Thiopental Na has been associated with more rapid post-operative recovery including less nausea/vomiting without adverse effects on pregnancy outcome[8].

Liu et al in their study conclude that anesthesia with Propofol combined with fentanyl may reduce the maintenance dosage of Propofol, shorten the time of consciousness recovery during oocyte retrieval with ultrasound guidance, and can be helpful for the patients, early recovery and discharge from hospital[29].

In present study Propofol offered faster recovery time from anesthesia than Thiopental Na(15+/-3min vs.25+/_5min) that was statistically significant(P<0.05).

CONCLUSION

Propofol offered lower incidence of PONV and a quick recovery from sleep without any adverse effects on pregnancy outcome in ART cycle.

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