



EARLY FETAL REDUCTION BY MECHANICAL DISRUPTION THROUGH A TRANSVAGINAL ULTRASOUND GUIDED APPROACH: EFFICACY AND PREGNANCY OUTCOME

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Abstract

Background: Although multiple pregnancy rate in natural conception is less than one percent, this increases significantly in assisted reproductive cycles. The number and rate of multiple pregnancies have increased over the past two decades. **Aim:** This study was carried out to compare safety and efficacy of multifetal pregnancy reduction by transvaginal route, using mere mechanical disruption, at an early gestational age (6 weeks – 9weeks + 6days) VS KCL injection through a transvaginal ultrasound guided approach in achieving fetal reduction and to observe the pregnancy outcome after fetal reduction using these 2 methods. **Methods:** This was an observational study on 50 pregnant women –with multifetal pregnancy achieved by ARTs- were recruited from the Kasr Al-ainy hospital and private infertility center (Riyadh Fertility and Reproductive Health center). Cases were randomize in to **Group A** :The needle was introduced into the desired gestational sac, then into the fetal cardiac region, and **Group B**:The injecting needle tip was introduced into the cardiac region and 0.5 ml of potassium chloride (KCL) was injected. **Results:** fetal reduction with “Mechanical disruption” procedure shows better outcomes compared to the “KCL injection” procedure; as it gave a higher percentage of take-home babies (75% vs. 58.33%), and less percentages of immediate loss (16.6% vs. 25%), miscarriage (5% vs. 9 %), and extreme prematurity (5.0% vs. 12.5%). **Conclusion:** we suggest that the early transvaginal mechanical non-KCl method is a better option for MFPR. We believe that it should be considered as the first choice modality in the majority of centers.

Keywords: Pregnancy Reduction, Multifetal; Pregnancy, Multiple; Reproductive Technology, Assisted; Pregnancy Outcome.

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Introduction

Multiple pregnancies being high-risk pregnancies are frequently complicated by preterm delivery, low birth weight, pre-eclampsia and increased perinatal morbidity and mortality. (1)

Such patients also require more operative interference and prolonged hospital stay for both the mother and the preterm baby thus mounting hospital expenditures. Severe prematurity has been reported to occur in one fourth of triplets, and are associated with higher perinatal morbidities especially cerebral palsy.(2)

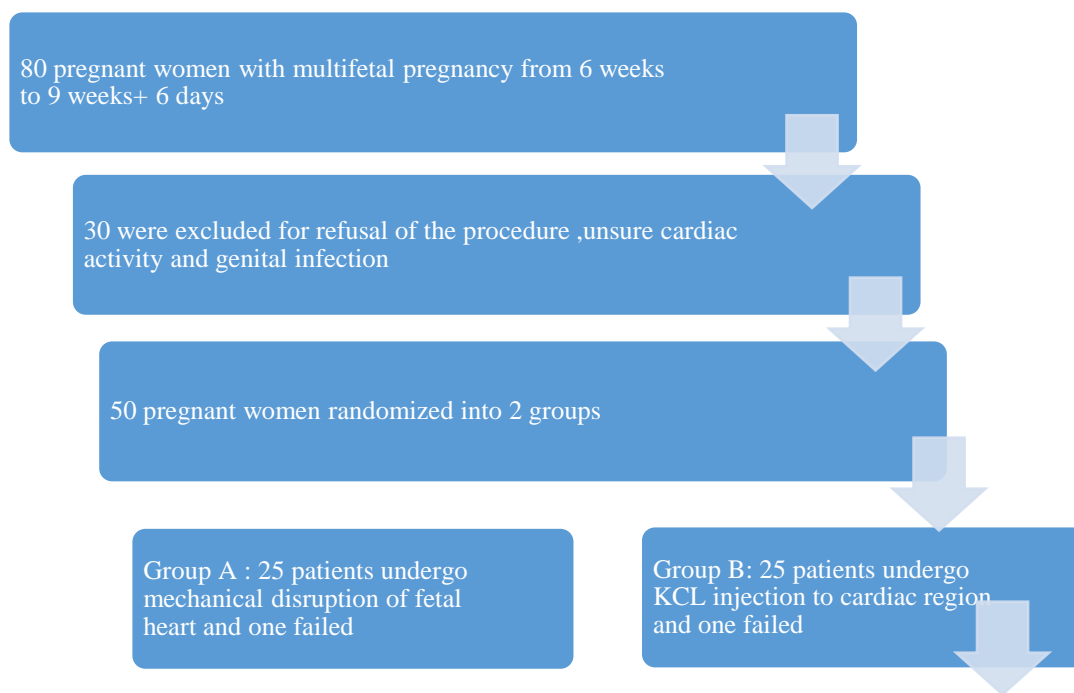
Decades of data have shown the incidence of prematurity and related sequelae directly correlate with fetal number (3).

In the UK, the single embryo transfer policy has reduced the incidence of multifetal gestation from 26.6 % in 2008 to 20.1 % in 2011. Also, in the US the ASRM (American society of reproductive medicine) has revised the guidelines to optimize the

number of transferred embryos during IVF. However in Egypt, transfer of 3 to 4 embryos is still practiced (4).

The procedure of fetal reduction aims to decrease the occurrence of maternal and perinatal morbidities related to multifetal gestations. It can be carried out transvaginally or transabdominally under ultrasound guidance. It may be done by potassium chloride injection through needle injection, mere mechanical disruption by a needle, or by radiofrequency ablation (5).

This study was carried out to compare safety and efficacy of multifetal pregnancy reduction by transvaginal route, using mere mechanical disruption, at an early gestational age (6 weeks – 9weeks + 6days) VS KCL injection through a transvaginal ultrasound guided approach in achieving fetal reduction and to observe the pregnancy outcome after fetal reduction using these 2 methods.



Flow chart: Failure of the procedure means persistence of the cardiac activity of the fetal heart after 3 to 4 trials of mechanical disruption in the desired gestational sac or injection of KCL in the cardiac region 24 hours postoperative.

Materials and methods

This Observational study on 50 pregnant women with multifetal pregnancy achieved by ARTs between August 2017 – March 2019

Inclusion criteria: Pregnant women with multifetal pregnancy (3 fetuses or more), Pregnant women age range from 28-33 years and BMI from 24-35, Pregnant women from 6 weeks to 9 weeks + 6 days calculated from the day of embryo transfer.

Exclusion criteria: Pregnant women who refused embryo reduction, Pregnant women who have any contraindication to KCL injection as known hypersensitivity, hyperkalemia and Pelvic or genital infection

Methodology in details

50 pregnant women –with multifetal pregnancy achieved by ARTs- were recruited from the Kasr Al-ainy hospital and private infertility center (Riyadh Fertility and Reproductive Health center).

All patients were subjected to: Full detailed history and examination. Informed written consent and consulted extensively about the potential risks for reduction procedures. Transvaginal ultrasonography for determination of number and site of gestational sacs, fetal size and fetal heart activity

Fetal reduction as follows: General anaesthesia using propofol 1%, lithotomy position, Sterilization of the vagina by povidone iodine, single injection of antibiotic prophylaxis intravenously, Transvaginal ultrasound in order to determine the embryos

number, site, size and cardiac activity, so that the gestational sac(s) chosen for reduction was the smaller one(s) and away from the lower uterine cavity Cook's embryo reduction needle was introduced through the posterior or lateral vaginal fornix using a guide mounted on a sterilised vaginal probe, aided by the biopsy guide on the ultrasound machine screen. The 50 pregnant women were randomized using pure randomized controlled trials and allowing chance to select them into one of the two groups (group A and Group B), it can be assumed that any confounding variables are cancelled out to reduce bias as much as possible. **Group A:** The needle was introduced into the desired gestational sac, then into the fetal cardiac region, aiming at mechanical disruption of the fetal heart till asystole is achieved, and may be aided by partial or total suction of the fetus, using suction device attached to the embryo reduction needle. **Group B:** The injecting needle tip was introduced into the cardiac region and 0.5 ml of potassium chloride (KCL) was injected. Confirmation of cessation of fetal heart activity after 5 minutes

Rescanning by transvaginal ultrasonography after 24 hours then after 1 week to confirm cessation of fetal heart activity in the desired gestational sac(s) No postoperative treatment was prescribed. All patients left the hospital on postoperative day 1.

All patients was then followed up till delivery for: Vaginal spotting or bleeding, infection, Miscarriage,

occurrence of complications related to multifetal pregnancy during their antenatal care e.g. gestational diabetes, hypertension, preeclampsia, etc, gestational age at birth and fetal birth weight

Possible Risk (mention if there is any risk or not): Spotting, miscarriage, failure of the procedure

Primary outcomes (Most important outcomes to be assessed): Success of the procedure i.e. successful fetal reduction which means leaving two embryos in place after reduction, a simple procedure, devoid of any risk to the mother, associated with a very low risk of infection and with no effect on the remaining fetuses (6).

Secondary outcome parameters (other outcomes to be assessed): Rate of miscarriage, time of the fetal reduction (minute/gestational sac), post-operative vaginal spotting or bleeding, occurrence of complications related to multifetal pregnancy e.g. gestational diabetes, hypertension, preeclampsia, etc ..., Gestational age at birth and fetal birth weight

Sample size: As considered the primary outcome, sample size calculation was done using the comparison of incidence of success of embryo reduction between mechanical and KCL use. Calculation was done based on comparing 2 proportions from independent samples in a prospective study using Chi test, the α -error level was

fixed at 0.05, the power was set at 80% and the intervention groups (case: control) ratio was set at 1. As previously published, the incidence of success of embryo reduction in mechanical group was 90% while it was 34% in KCL group. Accordingly, the minimum optimum sample size should be 11 participants in each arm. Sample size calculation was done using PS Power and Sample Size Calculations software, version 3.0.11 for MS Windows (William D. Dupont and Walton D. Vanderbilt, USA).

Results

In this study, two procedures for achieving fetal reduction – guided by transvaginal ultrasound Potassium Chloride (KCL) injection versus mechanical disruption – were compared for the efficacy, complications and pregnancy outcome.

As Table 1 show, 50 women with multifetal pregnancy, achieved by ARTs (25 per group), underwent the fetal reduction procedures. Twenty percent of women were multigravida while 80% were primigravida, with equal distribution in both study groups (p -value > 0.05). The study included 74% triplets and 26% quadruplets, with no statistically significant difference between groups regarding their distribution.

Table 1 Distribution of participants according to demographic data and pregnancy characteristics in both groups

	KCL injection	Mechanical Reduction	P value
Age	30.12 ± 1.13 (28 - 32)	30.84 ± 1.46 (29 - 33)	0.057
BMI	30.12 ± 1.13 (28 - 32)	30.12 ± 1.13 (28 - 32)	1.00
Type of infertility			
Primary	20 (80%)	20 (80 %)	1.00
Secondary	5 (20%)	5 (20%)	
Protocol used			
Antagonist	19 (76%)	18(72%)	0.747
Long	6 (24%)	7 (28%)	
Day of embryo transfer			
Day 3	4 (16%)	5 (20%)	0.842
Day 5	21(84%)	20(80%)	
Gestational age	7.64 ± 0.49 (7 - 8)	7.0 ± 0.76 (6-8)	Mean difference 0.640 0.001*

Table 2 describes the different pregnancy outcomes among women underwent the two fetal reduction procedures. In this study, fetal reduction with “Mechanical disruption” procedure shows better outcomes compared to the “KCL injection” procedure (**Figure 2-4**); as it gave a higher

percentage of take-home babies (75% vs. 58.33%), and less percentages of immediate loss (16.6% vs. 25%), miscarriage (5% vs. 9 %), and extreme prematurity (5.0% vs. 12.5%). Although these differences are of clinical significance, they were not statistically significant.

Table 2: describes the different pregnancy outcomes among women underwent the two fetal reduction procedures.

Pregnancy characteristics		Fetal Reduction Methods		Total	p-value
		KCL Injection	Mechanical		
Number of pregnancies	Multi	5 (20.0%)	5 (20.0%)	10 (20.0%)	1.00
	Primi	20 (80.0%)	20 (80.0%)	40 (80.0%)	
Number of fetuses in current pregnancy	Triplet	19 (76.0%)	18 (72.0%)	37 (74.0%)	0.747
	Quadriplet	6 (24.0%)	7 (28.0%)	13 (26.0%)	

Data presented as: Frequency (%)

Note: Mean \pm SD (Range)

*. Statistically significant p-value (<0.05)

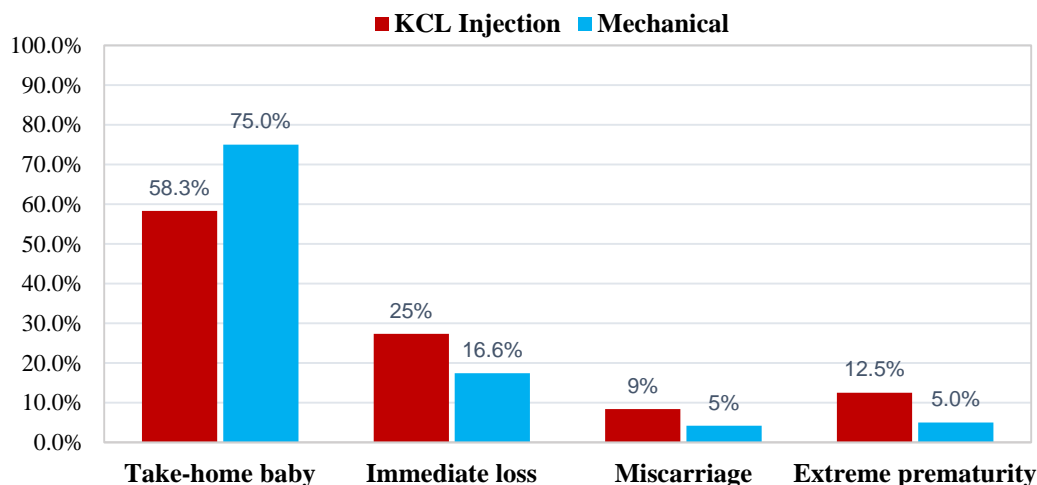


Figure 1: Different pregnancy outcomes in 'KCL' versus 'Mechanical' groups

Regarding birth characteristics, **Table 3** shows that babies of women underwent "Mechanical disruption" were born slightly earlier than babies of

women in the "KCL injection" group, however, it was not a statistically significant difference (mean difference: 0.24 week, p-value > 0.05).

Table 3: Distribution of fetal weight and age at-birth in both groups

	Fetal Reduction Methods		Mean Difference	p-value
	KCL Injection	Mechanical		
Gestational age at birth (weeks)	34.19 \pm 3.27 (26 - 37)	33.95 \pm 4.38 (27 - 37)	0.238	0.858
Birth weight (gm)	2135.63 \pm 502.35 (900 - 2600)	2181.25 \pm 489.85 (1100 - 2650)	-45.625	0.835

Note: Mean \pm SD (Range)

The occurrence of different post-operative complications following fetal reduction with "Mechanical disruption" versus "KCL injection" procedures. Premature rupture of membranes (PROM), vaginal spotting, and cervical

incompetence were more frequent among participants who underwent "KCL injection" compared to "Mechanical disruption"; (37.5% vs. 21.1%; 33.3% vs. 16.7%; 13.3% vs. 10.5%, respectively) (**Figure 2**).

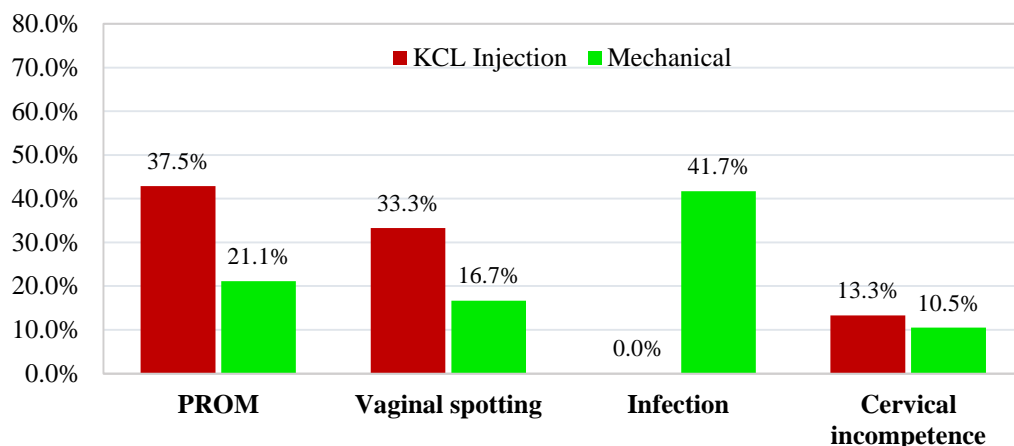


Figure 2: Different post-operative outcomes in 'KCL' versus 'Mechanical' groups

Table 4 compares the occurrence of other complications related to multifetal pregnancy in both study groups. Congenital anomalies and gestational diabetes occurred more frequently

among women underwent fetal reduction with the mechanical method compared to KCL injection method (5.3% vs. 0%; 10.5% vs. 0%, respectively) (Table 2-6).

Table 4: Distribution of the complications related to multifetal pregnancy in both groups

Complications related to multifetal pregnancy	Fetal Reduction Methods		p-value	Relative Risk (RR)	95% CI
	KCL Injection	Mechanical			
Congenital anomalies	0	1/19 (5.3%)	1.00 ^a	0.42	0.02 – 9.55
Gestational Diabetes	0	2/19 (10.5%)	0.492 ^a	0.25	0.01 – 4.85
Hypertension	3/16 (18.7%)	2/19 (10.5%)	0.835	1.77	0.70 – 4.48

^a. Fisher's Exact Test

DISCUSSION

We report our experience with 50 consecutive embryo reductions performed using either mechanical disruption or a KCL injection method. Our objective is to suggest guidelines for patient counseling and management of multifetal pregnancies using embryo reduction. We shall address the following questions: (1) what is the procedure of choice in terms of miscarriage risk, perinatal outcome more effective and easier; (2) and when is selective termination of clearcut benefit to patients??

Both mechanical methods and potassium chloride are equally effective agents for fetal reduction; however it appears that there are few advantages with each. The patients exposed to mechanical methods have lesser percentage of spontaneous miscarriage, prematurity.

Also, mechanical methods allow better fetal outcome with higher percentage of takehome babies despite early delivery.

Majority of second trimester reductions are done by transabdominal route either mechanically or with KCl or NaCl. Multifetal pregnancy reduction can be performed transcervically, transvaginally or transabdominally. Transcervical method involves mechanical dilatation of cervix, followed by

embryonic aspiration with karmans cannula or metal cannula. This method is no longer used because of the increased risk of chorioamnionitis, miscarriage, spotting.

We conducted this study on 50 pregnant women with multifetal pregnancy achieved by ARTs to observe the efficacy of mechanical disruption of the fetus through a transvaginal ultrasound guided approach in achieving fetal reduction and to observe the pregnancy outcome after fetal reduction using this method.

Twenty percent of the included women were multigravida while 80% were primigravida, with almost equal distribution in both study groups (p=1). The study included 74% triplets and 26% quadruplets, with no statistically significant difference between groups regarding their distribution (p=0.747).

All patients were subjected to Transvaginal ultrasonography for determination of number and site of gestational sacs, fetal size and fetal heart activity then fetal reduction either by Potassium Chloride (KCL) injection or transvaginal ultrasound-guided mechanical disruption (25 per group).

All patients were then followed up for Vaginal spotting or bleeding, Infection, Miscarriage,

Occurrence of complications related to multifetal pregnancy during their antenatal care e.g. gestational diabetes, hypertension, preeclampsia, etc ..., Gestational age at birth & Fetal birth weight In current study, both study groups did not show a statistically significant difference regarding maternal age (30.12 ± 1.13 in KCL group versus 30.84 ± 1.46 in Mechanical group $p=0.057$). However, the gestational age at the procedure in the KCL group (7.0 ± 0.76) was **significantly greater** than in mechanical group (7.0 ± 0.76), with a mean difference of 0.64 week ($p<0.001$).

In agreement with our study, among one hundred and forty-eight patients with multiple pregnancies resulting from assisted reproduction programs and underwent MFPR were divided into 'KCl', and 'non- KCl' groups and included in study by **Lee et al., (7)** the mean age of the subjects was 30.6 ± 2.9 yr. Maternal ages and characteristics of the MFPR procedures were not different among the groups.

Also, **Mansour RT et al., (8)** performed a study on 75 patients with high-order multiple pregnancies resulting from assisted reproduction. Controls were 40 non-reduced twin pregnancies and 22 high-order multiple gestations. Reduction was performed using KCl as a cardiotoxic agent at an earlier gestational age (approximately 7 weeks).

Intracardiac puncture without injection of any agent has also been reported by **Iberico et al., (9)** study on a total of 149 multifetal pregnancies was reduced to twins ($n = 134$) or singletons ($n = 15$) at early gestational age (7.8 ± 0.8 weeks).

In this study, fetal reduction with "Mechanical disruption" procedure shows better outcomes compared to the "KCL injection" procedure; as it gave a higher percentage of take-home babies (75% vs. 58.33%), and less percentages of immediate loss (16.6% vs. 25%), miscarriage (5% vs. 9%), and extreme prematurity (5.0% vs. 12.5%). Although these differences are of clinical significance, they were not statistically significant ($p>0.05$). In other words, women underwent "KCL injection" were 22% less likely to have take-home babies compared to the "Mechanical disruption" procedure, while they were 57% more likely to have immediate loss, and more than two times more likely to have miscarriage or extreme prematurity.

And take home baby rate was 79.1% in reduced group done by intracardiac puncture followed by manual aspiration of embryonic parts till asystole according to study by **Gunasheela et al., (10)**

Berkowitz RL et al., (11) presented the outcome of 200 consecutive multifetal pregnancies in whom procedures were performed in the first trimester by the transabdominal injection of potassium chloride. 16 of the 19 complete pregnancy losses occurred more than 4 weeks after the reduction procedure had been performed.

And other studies had used potassium chloride as in our study and recommended that, care has to be taken while using KCl. If the KCl solution accidentally reaches the amniotic fluid of the remaining embryos, this could result in a total pregnancy loss.

Also, as reported by **Shalev et al., (12)** The major complication by kcl after embryo reduction is miscarriage. The rate of miscarriage after embryo reduction varies from 4% to 33%.

But in disagreement with our study, **Mansour et al. (8)** conducted a prospective controlled study, included 75 patients with higher order pregnancies from assisted reproduction technique done using potassium chloride in 30 cases and last 45 cases were done by modified mechanical method, by aspirating. Controls were 40 non-reduced pregnancies. The miscarriage rate, fetal wastage rate were similar.

This study shows that babies of women underwent "Mechanical disruption" were born slightly earlier (33.95 ± 4.38), than babies of women in the "KCL injection" group (34.19 ± 3.27) however, it was not a statistically significant difference (mean difference: 0.24 week, p -value= 0.858). Also, babies in the "Mechanical disruption" group had a slightly higher birth-weight (2181.25 ± 489.85) than babies in the "KCL injection" group (2135.63 ± 502.35), but it was also not a statistically significant difference (mean difference: 45.6 gm, p -value=0.835)

According to **Gunasheela et al., (10)** study, the mean birth weight in reduced group done by intracardiac puncture followed by manual aspiration of embryonic parts till asystole is 2.2 kg which is quietly similar to our study.

Mansour et al., (8) study on 75 patients with high-order multiple pregnancies resulting from assisted reproduction. Controls were 40 non-reduced twin pregnancies. Reduction was performed using KCl as a cardiotoxic agent, 41 patients delivered between 32 and 39 weeks of gestation (mean \pm -SD, 36.9 ± 2.45 weeks). The mean (\pm -SD) birth weight was $2,450.51 \pm 235.44$ g. The mean gestational age, and mean birth weight were similar in reduced and non-reduced twins.

Hartoov et al., (13) using an intracardiac injection of potassium chloride, the mean gestational age at delivery was 36.6 ± 2.2 weeks (range 31–40 weeks). The mean birth weight was 2370 ± 614 g (range 1510–3250 g).

In agreement with our finding, the **Lee et al., (7)** study was a retrospective comparative study; Mean gestational ages at delivery and birth weights were not statistically different between KCl and non-KCl groups.

Although most of the studies have reported improved outcomes with fetal reduction, 2 studies have contradictory results. **Boulot et al., (14)** reported that the mean gestational age and birth

weight were significantly lower in twins from reduced group than in non-reduced group, suggesting that reduction to twins may increase the risk of premature labour and birth.

In current study, Premature rupture of membranes (PROM), vaginal spotting, and cervical incompetence were more frequent among participants who underwent “KCL injection” compared to “Mechanical disruption”; (37.5% vs. 21.1%; 33.3% vs. 16.7%; 13.3% vs. 10.5%, respectively). In other words, women underwent “KCL injection” procedure had 2 times greater risk for developing PROM and vaginal spotting, as well as 27% greater risk for cervical incompetence, compared to the “Mechanical disruption” procedure. It has been suggested that the development of an inflammatory response to the resorbing dead fetoplacental tissue with subsequent release of cytokines and stimulation of prostaglandins is a cause of pregnancy loss, preterm delivery, and other complications following MFPR in those studies were performed by KCl injection.

However, fetal reduction with the **mechanical method** was associated with more frequent post-operative infection compared to KCl injection procedure (4.17% vs. 0%). Although these findings are of clinical significance, they were not statistically significant (p -value >0.05).

In agreement with us, the **Lee et al., (7)** suggest that the use of KCl for MFPR may cause or aggravate the inflammatory process and induce PPROM and preterm birth but the difference not significant between KCl and non-KCl groups. PPROM occurred significantly more frequently in KCl groups than in non-KCl groups (27.6% vs. 9.7%, $p=0.019$).

And in study by **Talwar et al., (15)** the embryo reduction was carried out in 52 cases of triplets or higher order pregnancies by mechanical disruption. They found that, mechanical disruption of the gestational sac may be associated with an increased incidence of abortions due to infection introduced from the cervix or cervical incompetence brought about by cervical dilatation.

Also, according to **Gunasheela et al., (10)** using mechanical methods among fetal reduction, 3 patients aborted within a week of fetal reduction. All of them had spotting after cervical encirclage. The obstetric and medical complications in control group were more compared to reduced group.

In current study, Congenital anomalies and gestational diabetes occurred more frequently among women underwent fetal reduction with the mechanical method compared to KCl injection method (5.3% vs. 0%; 10.5% vs. 0%, respectively). In other words, women underwent “KCL injection” procedure had 58% less risk for babies with congenital anomalies, and 75% less risk for developing gestational diabetes; compared to

women in the “Mechanical disruption” group. However, they were at 77% greater risk for hypertension compared to women in the “Mechanical disruption” group.

However, hypertension was more frequent among women in the “KCl injection” group compared to those in the “Mechanical disruption” group (18.7% vs. 10.5%). Nevertheless, these differences were not statistically significant despite its clinical implication.

Similarly, the **Lee et al., (7)** study showed that, Fetal and maternal complications, such as fetal growth restrictions, discordant twins, congenital anomalies, gestational hypertension, and cervical incompetence were not different between KCl and non-KCl groups (27.6% vs. 9.7%, $p=0.019$).

Also, **Iberico et al., (9)** reported that, Potassium chloride is widely used for MFPR, but the safety and efficacy of this agent are debatable. Cases of anencephaly and limb amputation have been reported, and total pregnancy loss may be resulted if the KCl solution accidentally reaches the amniotic fluid of remaining fetuses.

CONCLUSION

both mechanical methods and potassium chloride are equally effective agents for fetal reduction; however it appears that there are few advantages with each. The patients exposed to mechanical methods have lesser percentage of spontaneous miscarriage, prematurity. Also, mechanical methods allow better fetal outcome with higher percentage of takehome babies despite early delivery.

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