

ORIGINAL ARTICLE

A Randomized Controlled Trial to Compare the Efficacy of Three Different Methods of Maternal Hydration for Oligohydramnios*Neelamma Patil^{1*}, Abhigna V¹**¹Department of Obstetrics and Gynecology, Shri B.M. Patil Medical College Hospital and Research Center, BLDE (Deemed to be) University, Vijayapur-586103 (Karnataka) India***Abstract:**

Background: Oligohydramnios is defined as an Amniotic Fluid Index (AFI) of less than normal for that gestational age. It is mainly associated with increased perinatal morbidity and mortality due to cord compression, fetal distress, pulmonary hypoplasia. So, an effective medical therapy is very important to prevent the complications. **Aim and Objectives:** To compare efficacy of maternal hydration with oral water, 1L of Ringer Lactate (RL) + 1L of 5% Dextrose (5% D) and 2L of 0.45% Normal saline (0.45% NS) in increasing AFI in patients with oligohydramnios. **Material and Methods:** Patients who had been diagnosed as oligohydramnios (with AFI<8cm) by Ultrasonography (USG) were included in the study. Both Fetal Growth Restriction (FGR) with oligohydramnios and idiopathic oligohydramnios were studied. Totally 108 cases were allocated into 3 groups depending on the computer generated randomized table. Group A was given oral hydration i.e., 2L of water in 2 hours. Group B received 1L RL+ 1L 5% D in 2 hours intravenously and Group C was given 2L 0.45% NS in 2 hours intravenously. AFI and Symphysiofundal Height (SFH) was assessed after 2 hours and 24 hours after the hydration therapy. **Results:** All the types of hydration therapy had significant increase in AFI and SFH at 2 hours and 24 hours. In group A, mean increased from 4.91 ± 1.58 to 5.88 ± 1.86 and 6.49 ± 2.22 at 2 hours and 24 hours respectively. Similarly in group B, mean increased from 4.98 ± 1.86 to 5.79 ± 1.89 , 6.18 ± 2.23 at 2 and 24 hours respectively. In group C, mean value increased from 5.58 ± 1.31 to 7.32 ± 1.40 , 8.32 ± 1.77 at 2 hours and 24 hours. There was significant increase in group C when compared to other two groups and there

was no statistically significant difference between group A and group B. There was significant rise in SFH in all the three groups at 2 hours and 24 hours. Both FGR with oligohydramnios and idiopathic oligohydramnios responded well to any type of hydration, but 0.45% NS was significantly better in unexplained oligohydramnios. None of the patients had any major side effects. **Conclusion:** Both oral and IV hydration with hypotonic solution increases the level of amniotic fluid in cases of oligohydramnios. But 0.45% NS was shown to be significantly better than oral hydration and IV hydration with RL+5% D especially in idiopathic oligohydramnios. SFH can be used to assess the amount of amniotic fluid clinically whenever AFI by ultrasound is not feasible.

Keywords: Oligohydramnios, Amniotic Fluid Index, Maternal Hydration, Oral Hydration, Intravenous Hydration

Introduction:

Oligohydramnios is defined as an Amniotic Fluid Index (AFI) of less than normal for that gestational age [1]. It has an incidence of 8.5% to 15.5%. Oligohydramnios is mainly associated with increased perinatal morbidity and mortality due to cord compression, fetal distress, pulmonary hypoplasia [2, 3]. So, an effective medical therapy for oligohydramnios is very important to prevent these complications. Various treatments have been tried to improve AFI, like hydration therapy, amino acid infusion, amnioinfusion, and arginine granules [4-7, 2]. Among all, simple maternal

hydration has shown to increase amniotic fluid through reduction in maternal plasma osmolality which in turn leads to a raise in AFI. Hydration can be either oral or Intravenous (IV) Various fluids have been tried for maternal IV hydration like Normal Saline (NS), Ringer Lactate (RL), 0.45% Normal Saline (0.45% NS) and 5% Dextrose (5% D) [2, 3, 4, 8-11]. Oral hydration has shown to be more effective than IV hydration by various studies and also by cocharane review [12]. Among the intravenous fluids many have studied with 5% D, RL, NS. But NS has been shown to be not much effective [8, 12]. Both RL and 5% D have been studied separately by many authors as hypotonic solutions and have shown increase in AFI. But patients receiving 5% D are at increased risk of hyperglycemia which can be dangerous in undiagnosed gestational diabetes mellitus. RL contains less sodium concentration compared to NS. The combination of RL and 5% D makes the fluid more hypotonic without the risk of hyperglycemia. So, we thought combining these 2 fluids can be more hypotonic and thus be more effective. One more hypotonic fluid which has not been studied much was 0.45% NS. So, we decided to study the efficacy of these two types of fluids i.e., combination of RL and 5% D and 0.45% NS as compared to oral hydration.

Material and Methods:

Pregnant women were admitted in BLDE University, Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India were studied. With a error of 99% and power of 85%, statistical calculations showed that a total of 108 patients will be required to be studied.

The formula used was

$$n = \frac{(Z + Z)^2 \times 2 \times (SD)^2}{d^2}$$

All the patients who had been diagnosed with oligohydramnios (with AFI<8 by Phelans method [5]) by Ultrasonography (USG) were included. They were divided into 3 groups depending on the computer generated randomized table with seed number 16546. Informed consent was taken from all the participants. The study was approved by Institutional Ethics Committee. Detailed history of all the patients was taken and complete examination was done. Patients were screened for anemia (Hb %), DM (oral glucose challenge test), Preeclampsia (blood pressure charting, urine albumin).

Inclusion criteria were antenatal cases between 18years and 35 years, gestational age from 28-41 weeks, singleton pregnancy, FGR with oligohydramnios and idiopathic oligohydramnios. Exclusion criteria were hypertensive disorders in pregnancy, pre-existing or gestational diabetes, anaemia (Hb < 8gm%), premature rupture of membranes, multiple gestation, cardiovascular disorder, maternal pulmonary disorder, oligohydramnios due to fetal congenital anomalies, patients on non steroidal anti inflammatory drugs.

All the patients were divided into 3 groups with 36 patients in each group.

Group A: Oral hydration i.e., 2L of water in 2 hours (hypotonic).

Group B: 1L R.L+ 1L 5% D in 2 hours intravenously.

Group C: 2L 0.45% NS in 2 hours intravenously.

USG was done and AFI was noted by Phelan method [13] at admission (Before Hydration Therapy). Repeated 2 hours after the hydration therapy and repeated after 24 hours of the hydration therapy. Baseline SFH was noted at the time of admission and was repeated at 2hours and 24 hours along with AFI.

Results:

There was no significant difference in the baseline parameters (table 1) i.e., maternal age, parity, gestational age, blood pressure and baseline AFI. In all the three groups the average amniotic fluid index at 2 hours and 24 hours was significantly higher compared to baseline amniotic fluid index ($P < 0.001$) and 24 hours was significantly higher compared to 2 hours amniotic fluid index ($P < 0.001$) (Table 2). The average 2 hours and 24 hours amniotic fluid index was significantly higher in group C compared to groups A and B ($P < 0.05$). The average 2 hours and 24 hours amniotic fluid index did not differ significantly between Groups A and B ($P > 0.05$). In all groups the average Symphysiofundal Height (SFH) at 2 hours and 24 hours was significantly higher compared to baseline SFH ($P < 0.001$). In Group A and B the average SFH at 24 hours was significantly higher compared to 2 hours SFH ($P < 0.01$). But in group C there was no significant difference between 2 hours and 24 hours suggesting that the AFI has improved by 2 hours and remained same for 24 hours.

In idiopathic oligohydramnios and FGR with oligohydramnios groups the average AFI and SFH at 2 hours and 24 hours was significantly higher compared to baseline amniotic fluid index

($P < 0.001$) with any type of hydration. In idiopathic Oligohydramnios, all groups showed significant improvement at 2 hours and 24 hours. But group C did better than group A and group B (Table 3). In FGR with oligohydramnios Group A and group C showed significant difference from baseline at 2 hours and 24 hours. But only few cases with FGR with oligohydramnios were studied.

The number of cases of persistent oligohydramnios (AFI < 8 cm) at 2 hours and 24 hours was significantly higher in Groups A and B compared to Group C. Patients whose AFI remained < 8 cm after 24 hours after hydration, repeat hydration was given according to randomization table on the same patient. So, one patient received more than one type of treatment. 43 patients received only one type of hydration, 23 patients received hydration twice and 3 patients received hydration thrice. 2 patients who received one type of hydration and 2 patients who received two types of hydration could not be followed up (total 6 cases). So, we could study maternal and perinatal outcome of only 41 patients and there was no significant difference among the three groups. But less number of patients had LSCS and NICU admissions in group C. No significant side effects were noted except 4 cases of nausea and vomiting in oral hydration group.

Table 1: Comparison of Baseline Parameters among Three Groups

Parameters	Group A (n=36)	Group B (n=36)	Group C (n=36)	P-value
Maternal age (years)	22.9 ± 4.1	23.9 ± 4.2	23.4 ± 4.1	0.66
Parity	1.4 ± 0.50	1.4 ± 0.5	1.36 ± 0.49	0.77
Gestational age (weeks)	37.4 ± 2.6	37.1 ± 2.0	36.8 ± 2.9	0.60
Systolic BP	122.0 ± 3.3	122.9 ± 3.9	122.8 ± 4.4	0.56
Diastolic BP	82.4 ± 4.1	81.2 ± 3.7	81.7 ± 4.2	0.43

Table 2: Inter-group and Intra-group Comparison of AFI and SFH across Three Study Groups

	Group A (n=36)	Group B (n=36)	Group C (n=36)	Inter Group Comparisons (P-value)		
				Group A v/s Group B	Group A v/s Group C	Group B v/s Group C
AFI						
Baseline	4.91 ± 1.58	4.98 ± 1.86	5.58 ± 1.31	0.999	0.198	0.301
2-Hr	5.88 ± 1.86	5.79 ± 1.89	7.32 ± 1.40	0.999	0.002	0.001
24-Hr	6.49 ± 2.22	6.18 ± 2.23	8.32 ± 1.77	0.999	0.001	0.001
Intra-Group Comparison (P-value)						
Baseline v 2-Hrs	0.001	0.001	0.001			
Baseline v 24-Hr	0.001	0.001	0.001			
2-Hrs v 24-Hr	0.001	0.001	0.001			
Symphysiofundal Height (SFH)						
Baseline	32.7 ± 2.1	32.8 ± 1.8	32.8 ± 1.9	0.999	0.999	0.999
2-Hr	34.3 ± 2.2	33.6 ± 1.9	34.0 ± 1.9	0.473	0.999	0.999
24-Hr	33.8 ± 2.2	33.3 ± 1.9	33.9 ± 1.8	0.699	0.999	0.562
Intra-Group Comparison (P-value)						
Baseline v 2-Hr	0.001	0.001	0.001			
Baseline v 24-Hr	0.001	0.001	0.001			
2-Hrs v 24-Hr	0.005	0.001	0.312			

Values are Mean ± Standard deviation (SD). Inter-group comparisons are done using one-way analysis of variance (ANOVA) with Bonferroni's Post-Hoc test for multiple group comparisons. Intra-group comparisons are done using Paired 't' test. P<0.05 is considered to be statistically significant, P<0.01 is considered to be high significant, P<0.001 is considered to be extreme significant.

Table 3: Inter-group and Intra-group Comparison of Amniotic Fluid Index (AFI) across Three Study Groups in Idiopathic Oligohydramnios and FGR with Oligohydramnios

Amniotic Fluid Index (AFI)	Group A	Group B	Group C	Inter Group Comparisons (P-value)		
				Group A v/s Group B	Group A v/s Group C	Group B v/s Group C
Idiopathic oligohydramnios	n=25	n=31	n=29			
Baseline	4.86 ± 1.62	5.05 ± 1.74	5.64 ± 1.26	0.999	0.203	0.443
2-Hr	5.81 ± 1.94	5.91 ± 1.87	7.44 ± 1.30	0.999	0.002	0.003
24-Hr	6.46 ± 2.29	6.32 ± 2.24	8.54 ± 1.64	0.999	0.001	0.001
Intra-Group Comparison (P-value)						
Baseline v 2-Hr	0.001	0.001	0.001			
Baseline v 24-Hr	0.001	0.001	0.001			
2-Hrs v 24-Hr	0.001	0.001	0.001			
FGR with oligohydramnios	n=11	n=5	n=7			
Baseline	5.02 ± 1.56	4.52 ± 1.59	5.34 ± 1.59	0.999	0.999	0.999
2-Hrs	6.04 ± 1.76	5.10 ± 2.13	6.81 ± 1.79	0.999	0.999	0.387
24-Hr	6.58 ± 2.15	5.26 ± 2.18	7.40 ± 2.12	0.801	0.999	0.313
Intra-Group Comparison (P-value)						
Baseline v 2-Hr	0.001	0.120	0.001			
Baseline v 24-Hr	0.001	0.168	0.002			
2-Hrs v 24-Hr	0.021	0.614	0.041			

P<0.05 is considered to be statistically significant, *P*<0.01 is considered to be high significant, *P*<0.001 is considered to be extreme significant.

Table 4: Comparison of Maternal and Perinatal Outcome among 3 Groups (P value)

Mode of Delivery	Group A (n=12)		Group B (n=16)		Group C (n=13)		Inter Group Comparisons (P-value)		
	N	%	N	%	N	%	Group A v/s Group B	Group A v/s Group C	Group B v/s Group C
Mode of delivery									
Normal	3	25.0	5	31.3	7	53.8	0.999	0.226	0.274
LSCS	9	75.0	11	68.7	6	46.2			
Liquor									
Clear	9	75.0	7	43.8	10	76.9	0.136	0.999	0.130
Meconium	3	25.0	9	25.2	3	23.1			
NICU admission									
Required	3	25.0	8	50.0	2	15.4	0.253	0.645	0.114
Not Required	9	75.0	8	50.0	11	84.6			
APGAR									
1-Min	6.8 ± 0.6		5.9 ± 1.6		6.7 ± 0.8		0.139	0.999	0.253
5-Min	8.8 ± 0.6		8.0 ± 1.5		8.9 ± 0.6		0.115	0.999	0.096

P<0.05 is considered to be statistically significant, P<0.01 is considered to be high significant, P<0.001 is considered to be extreme significant.

Discussion:

Amniotic fluid volume is an important parameter in the assessment of fetal well-being. According to the present study, all the three hydration groups A, B, C have shown statistically significant improvement in AFI both at 2 hours and 24 hours compared to baseline AFI. But 0.45% NS proved to be better than oral and combined fluid of RL and 5% D. The effect was seen as early as 2 hours and remained for 24 hours and same effect was also

seen in SFH suggesting that if USG is not available we can assess the improvement in amniotic fluid by SFH. None of the previous studies have assessed this parameter.

Many of the previous studies have shown that the oral hydration is better than IV hydration. Even the Cochrane review in 2010 had concluded that oral hydration is better [4]. But in our study 0.45% NS was shown to be better than oral hydration.

Though oral hydration is easy, simple and cheap, it depends on the patient's compliance. If the patient does not drink water properly the effect may not be seen. So far there is only one study on 0.45% NS conducted by Rosenberg *et al.* [10]. It was not shown to be effective compared to placebo, may be because the effect was looked for too early i.e., 1 hour after hydration.

There are no studies in which both RL and 5% D are given among patients of a single group, but there are many studies where they have been studied individually.

A study conducted by Umber *et al.* concluded that maternal intravenous hydration (2L of 5% D) as well as oral hydration increases AFI equally [11]. Momina *et al.* conducted a study on 226 women and it was found that oral hydration was more effective than intravenous therapy group [1]. But in our study the effect of RL+5% D was equal to oral hydration. Shivkumar *et al.* [4] found that if IV fluids and IV infusion of amino acids, when given as a week regimen on alternate days, increased the short term AFI and also the foetal weight.

Out of 108 cases, 85 cases were idiopathic oligohydramnios and 23 cases were associated with FGR. Both idiopathic oligohydramnios and FGR with oligohydramnios groups showed significant improvement in AFI at 2 hours and 24 hours with any type of hydration therapy. Among idiopathic oligohydramnios all the three groups had significant improvement in AFI at both 2 hours and 24 hours compared to baseline. But 0.45% NS

showed statistically significant improvement. Among FGR cases, group A and group C showed significant increase in AFI. In group B there was no significant difference at 2 hours and 24 hours. But there was no significant difference among the three groups. May be the sample size in each group is too less to show the difference. The perinatal outcome did not vary significantly among the three groups. It may be due to less number of patients in each group. But apparently the outcome was better in 0.45% NS though not significant. May be studies with more number of patients in each group will be able to show the difference. No other clinically significant side effects of fluid overload were seen.

Limitations:

1. No cases with gestational age <30 and >41 weeks could be studied.
2. Oligohydramnios with antenatal complications were not included except FGR.
3. The duration of effect of hydration therapy beyond 24 hours was not studied.

Conclusion:

Our study strongly suggests that maternal hydration status has a definite role in amniotic fluid regulation. All types of maternal hydration therapies increased AFI and SFH at 2 hours and 24 hours. Among them 0.45% NS was significantly effective compared to RL+5% D and oral hydration in treatment of oligohydramnios. They had better perinatal outcome than other two groups though not statistically significant.

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