Zagazig University Medical Journal
www.zumj.journals.ekb.eg

Volume 29, Issue 1, January 2023, Page (337-341) Supplement Issue

Manuscript ID ZUMJ-1910-1594 (R3)

DOI **10.21608/zumj.2019.18331.1594**

ORIGINAL ARTICLE

The Feasibility of Amniopatch for Management of Mid-Trimester Rupture of Membranes

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Submit Date 2019-10-24
Revise Date 2019-12-08
Accept Date 2019-12-13

ABSTRCT

Background: Mid-trimester preterm premature rupture of membranes (PPROM), defined as rupture of fetal membranes before 28 weeks of gestation, complicates approximately 10-12% of all pregnancies. it is associated with very high perinatal mortality and morbidity. The causes of the mid-trimester PPROM are multifactorial. The management of PPROM requires a balance between the benefits of prolongation of the pregnancy and the risk of intra-amniotic infection and its consequences for the mother and infant. Many optional treatments had been discussed in this issue to improve fetal outcome, these include, expectant management, repeated amnioinfusion, and amniopatch, etc.
This study aimed to evaluate the effectiveness of amniopatch in the management of mid-trimester PROM.

Methods: This study was being carried out in the obstetrics and gynecology department, Zagazig university hospitals from January 2016 to December 2018. The study included 36 pregnant women with PPROM from 20 -28 wk. All patients after informed written consent underwent a complete clinical examination and laboratory investigations, and amniopatch was done under complete aseptic conditions.

Results: Out of 36 patients, only 13 cases showed partial success 36,1% (partial success was defined by sealing of membranes and temporary relieve of oligohydramnios). Of partial success cases there were 7 cases 53.8% re ROM again after sealing and 6 cases 46.2% enter in preterm labor despite sealing of membranes, and 23 cases failed 63.9% of which 18 cases missed abortion 78.2%, 3 cases inevitable abortion 13.1%, and 2 cases chorioamnionitis 8.7%.

Conclusion: Amniopatch has only a partial success rate in the management of mid-trimester PPROM.

Keywords: Amniopatch, mid-trimester preterm premature rupture of membranes.

INTRODUCTION

Fetal membranes are important for sterile intrauterine life, fetal development and growth[1]. It provides good protection for the fetus against trauma and infection [2]. Mid-trimester preterm premature rupture of membranes (PPROM), defined as rupture of fetal membranes before 28 weeks of gestation complicates approximately 10-12% of all pregnancies[3]. It is associated with very high perinatal mortality and morbidity[4]. Prolonged decrease of amniotic fluid volume at this critical gestational age is associated with bronchopulmonary hypoplasia (BPH) and skeletal deformities, also it increases the rate of perinatal sepsis, placental abruption and preterm labor[5]. Rupture of amniotic membranes is either produced traumatically by the needle during amniocentesis(iatrogenic), or it can occur spontaneously[4]. The etiology of pre-viable spontaneous PPROM is multifactorial, although intrauterine infection is known to be the most common identifiable cause [6].

The obstetric management options for Mid-trimester PPROM include termination of pregnancy, expectant management and aggressive intervention with cerclage, amnioinfusion, and amniopatch[7]. This study is about amniopatch as a trial for the management of PPROM. The amniopatch technique was first introduced by Quintero et al. in 1996[6]. It consists of infusion of platelets intraamniotic followed by cryoprecipitate, which provides fibrinogen, fibronectin, platelet-derived growth factors, TGF-beta, von Willebrand factor, factor VIII and factor XIII in high

concentrations, which may form a plug and seal the defected site [1].The aim of this study to evaluate the effectiveness of amniopatch in the management of mid-trimester PPROM.

METHODS

Sample size was calculated by open EPI to be 36 cases with confidence level 95% and power of test 80%. This study is a clinical trial and was being conducted at Zagazig university hospitals in the period from January 2016 to December 2018, a total of 36 pregnant females with mid-trimester PPROM underwent amniopatch procedure, in all cases the cause of PPROM was spontaneous. All patients were subjected to a detailed history, examination (general, abdominal and local) and investigations (laboratory, imaging, etc). Written informed consent was obtained from all patients and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. The diagnosis of PPROM was made by a history of the sudden gush of fluid per vagina and sterile speculum examination, this was followed by transabdominal ultrasound for accurate detection of amniotic fluid volume, exclusion of congenital anomalies and confirmation of gestational age. We counseled the patients about the potential benefits and risks of pregnancy continuation and offered the amniopatch procedure.

Laboratory investigations (CBC, CRP, urine analysis, liver and kidney functions) were done.

We exclude patients with chorioamnionitis, active vaginal bleeding or patients in active labor.

Under complete aseptic conditions, 22 gauge spinal needle was inserted intraamniotic very slowly ultrasound-guided in order to avoid any fetal injury, then 30 cc saline was injected in order to create the pocket in which the platelets(30 ml) and cryoprecipitate (20 ml) were infused, this was followed by infusion of another 20 cc saline in the same sitting before removing of the needle, a color Doppler was applied for accurate verification of needle site as infusion of saline can produce color signal. Over the following days, bed rest, prophylactic antibiotic therapy, and daily ultrasound monitoring for amniotic fluid volume were done, tocolytics and antenatal corticosteroid were administered when indicated. Successful amniopatch was defined as no further amniotic fluid leakage and maintenance/increase of amniotic fluid volume after the treatment. Failure of amniopatch treatment was defined as continuous amniotic fluid leakage after the procedure. Partial success was defined as a temporary stop of leakage followed by rerupture of membrane again before reaching maturity or preterm delivery despite sealing of membranes. Patients Clinical characteristics before performing an amniopatch included age, parity, gestational age at PPROM, were detected. Factors associated with the procedure included gestational age at amniopatch, PPROM-to amniopatch interval, AFI before and after the procedure were investigated.

Data collected throughout history, basic clinical examination, laboratory investigations, and outcome measures coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis. According to the type of data qualitative represented as number and percentage, the quantitative continuous group represented by mean ± SD, the following tests were used to test differences for significance; difference and association of qualitative variable by Chi-square test (X2). Differences between parametric quantitative independent groups by t- test, non-parametric by Mann Whitney and agreement by Kappa agreement. P- value was set at <0.05 for significant results & <0.001 for a highly significant result.

RESULTS

During the 3-years study period, 36 patients were diagnosed with PPROM at 20-28 weeks of gestation. Out of 36 pregnant females who underwent amniopatch only 13 cases showed a partial success(36.1%) and 23 cases showed a failure rate (63.9%). Partial success cases further subdivided into 7 cases rerupture of membranes again after sealing (53.8%), and 6 cases enter in preterm labor despite sealing of membranes (42.2%). Failed cases subdivided into 18 cases missed abortion(78.2%), 3cases inevitable abortion(13.1%), and 2 cases complicated by chorioamnionitis(8.7%), these results are shown in table (1).

Table(2)shows that there was a statistically significant increase in AFI from(2.32±0.95) before to (4.73±2.3) immediately after amniopatch.

The mean gestational age in this study was 26 weeks in partial success cases and 24 weeks in failed cases as in table(3).

Comparison was done between the success and failure group as regard the gestational age during the procedure , the time interval between PPROM and amniopatch and AFI before and after amniopatch, this showed that Failure cases significantly lower in GA, significantly lower regard AFI before and after amino patch, also failure group was significantly higher as regard prom to patch time as shown in tables(3,4,5).

Table (1): Outcome of the studied group:

partial success(stop leakage)	**NO(13)**	**36.1%**	**% from partial success cases**
Preterm labour despite healing of membranes	6		46.2%
Re-PROM after healing	7		53.8%
Failed cases(continuous leakage)	**NO(23)**	**63.9%**	% from failed cases
Missed abortion	18		78.2%
Inevitable abortion	3		13.1%
Chorioamnionitis and termination of pregnancy	2		8.7%

Table (2): Comparing AFI before and after amniopatch in the studied group:

Variable	**AFI before amnio patch**	**AFI after amnio patch**	**Wilcoxon signed rank test**	**p-value**
AFI **mean ± SD** **(Range)** **median**	2.32±0.95 (1-4) 2.5	4.73±2.3 (2.5-9) 4	8.7	0.001**

Table (3): Comparing between failed cases and partial success regarding age and gestational age:

Variable	**partial success (13)**	**failed cases (23)**	**t-test**	**p-value**
Age **mean ± SD (Range)** **Median**	28.4±2.4 (20-36) 27	30.1±5.4 (20-36) 29	1.7	0.08
Gestational age **mean ± SD** **(Range)** **Median**	25.8±1.3 (24-27) 26	23.3±1.8 (20-26) 24	4.2	**0.001****

Table (4): Comparing between failed cases and partial success regarding AFI before and after amniopatch:

Variable	**partial success (13)**	**failed cases (23)**	**t-test**	**p-value**
AFI before amnio patch **mean ± SD(Range)** **Median**	3.07±1.09 (1.5-4) 4	1.98±0.58 (1-3) 2	3.9	0.001**
AFI after amnio patch **mean ± SD** **(Range)** **Median**	6.2±2.7 (3-9) 8	3.89±1.4 (2.5-7) 3.5	3.4	0.002*
p-value^	0.003*	0.006*		

Table (5): Comparing between failed cases and partial success regarding PROM to amniopatch interval time:

Variable	partial success (13)	failed cases (23)	t-test	p-value
PROM to amnio patch interval time	5±1.2 (2-7) 5	9.7±2.4 (7-14) 10	5.1	0.001**

DISCUSSION

The study included 36 pregnant females from 20 – 28 wk gestational age with preterm premature rupture of membranes which was detected clinically and confirmed by investigations, all cases had spontaneous rupture of membranes. All patients were subjected to amniopatch after following the inclusion criteria and follow up was done in obstetrics and gynecology department Zagazig university hospitals.

Outcome after following up of patients showed that AFI significantly increases immediately after amniopatch with positive fetal pulsation in all cases, it increases from (2.32±0.95)before amniopatch to(4.73±2.3)after amniopatch. But this improvement did not continue as follow up in the following weeks showed that there was a high failure rate in the studied group, failure with continuous leakage of amniotic fluid was found in 23 cases(63,9%) and stop of leakage with partial success only in 13 cases(36,1%). No case has a complete success as no one complete pregnancy till term.

Factors associated with amniopatch treatment success or failure rate were investigated, these factors include, gestational age, AFI before amniopatch, the time interval between ROM and amniopatch. The success rate was associated with the larger gestational age before procedure, the larger the amniotic fluid index and the shorter the interval between ROM and the intervention.

In this study, the mean time interval between PPROM and amniopatch was 5 days in partial success cases and 10 days in failed cases and this shows a significant difference in the success rate as the shorter the time interval the better the success rate and these results match with **Gupta et al.,** [1], this was explained by the Longer lapse after PROM leads to less well defined, torned, rolled-up membranes and thus a larger defect than original.

In this study, there was statistically significant increase in AFI from(2.32±0.95) before to (4.73±2.3) after amniopatch, and it showed a significant difference between the failure group and the partial success group, success group was significantly higher as regard AFI before procedure and these results are in line with a cohort study done by **Sung JH et al**., [6]. However this dismatch with Feriance et al., [9] who represent a case report of 30years old pregnant female with a history of SPROM at 19 +1 wks, u/s revealed anhydramnios after laboratory investigation, amniopatch was done at 21+1 wks (2week interval after SPROM by autologous platelets and autologous cryoprecipitate). AF reaccumulation occur but after 3 days reROM occurs however not progress to anhydramnios Pregnancy ended by C.S at 33+1wks. This not agree with our results as it was done on anhydramnios and gave more prolongation of latency period till delivery from 21+1 week till 33+1 weeks, however, this is a case report and more studies must be done on more number of patients before using this method for management of mid-trimester ROM.In this study, the mean for gestational age before intervention in success group and failure group was 25.8±1.3 VS 23.3±1.8 respectively and this indicates the larger gestational age before amniopatch, the better outcome, this may be due to the nearer to the age of fetal viability.After following up reROM after sealing occur in 7 cases (53.8%) as in studies done by Feriance et al., *and Quintero et al.,* [9,10]. A study was done by *Chmait et al., Quintero* et al., and Pathak et al., [8,11,12] on amniopatch on iatrogenic ROM showed increase success rate in a large number of cases and this high rate of success is against our results, this may be due to their studies were on iatrogenic PROM. This study was on spontaneous PROM and all studies which showed complete success or increase rate of partial success were on iatrogenic PROM.

CONCLUSION

Amniopatch (intra-amniotic injection of platelets and cryoprecipitate) for mid-trimester rupture of membranes could not be used as a permanent solution for this uncontrolled problem especially in cases of spontaneous PPROM, as it did not significantly prolong latency period till delivery, and it did not significantly improve the outcome.

Financial Disclosures: Nothing to declare.

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To Cite:

Abdelkader, A, Lebda, I., Morad, M., Abdeldayem, H., Bessar,A., The Feasibility of Amniopatch for Manegement of Mid-Trimester Rupture of Membranes. *Zagazig University Medical Journal*, 2023; (337-341): -.doi: 10.21608/zumj.2019.18331.1594.