THERAPEUTIC TERMINATION OF SECOND TRIMESTER PREGNANCY: A COMPARISON OF EXTRA-AMNIOTIC FOLEY'S CATHETER BALLOON ALONE WITH THE COMBINED USE OF FOLEY'S CATHETER BALLOON AND EXTRA-AMNIOTIC INSTILLATION OF PROSTAGLANDIN F2-ALPHA.

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ABSTRACT

Objective: The aim of this study was to compare the efficacy, safety, adverse effects and cost effectiveness of extra-amniotic Foley's catheter balloon alone (group-I) with the combined use of Foley's catheter balloon and extra-amniotic prostaglandin F2-alpha (group-II) for termination of second trimester pregnancy.

Material and Methods: It was a comparative randomised trial carried out in obstetrics and gynaecology unit of Postgraduate Medical Institution, Lady Reading Hospital Peshawar, during 2002. Patients were randomly allocated to group-I, having odd admission numbers and group-II, having even admission numbers. Sixty-three patients having gestational age between 14 to 28 weeks and cervical score less than 4 were enrolled in the study, 33 for group-I and 30 for group-II. Indications for termination were either intra-uterine foetal death or congenital malformations incompatible with life. Both the groups had a size-16-F Foley's catheter passed through the internal OS and its balloon distended with 30 millilitres of distilled water. Group-II patient in addition received extra-amniotic prostaglandin F2-alpha (0.25mg/ml diluted solution), one ml at hourly interval, through the same catheter, till the expulsion of the balloon.

Results: Mean induction to products expulsion interval was significantly shorter in the combined use of Foley's catheter balloon and extra-amniotic

prostaglandin F2-alpha (PGF2-alpha) compared to the use of Foley's catheter balloon alone (16.50±8.823 versus 37.76±11.019 hours, P<0.005). The rate of successful uterine evacuation within 24 hours was also significantly higher in group-II (86.66% versus 6.06%, P<0.01). The incidence of vomiting (10%), diarrhoea (6.66 %) and uterine pain (10%) in group-II was not statistically significant (P>0.05), but the frequency of temperature of 100°F was significantly higher in group-I (23.64%) compared to group-II (3.33%). Group-II patient had shorter average hospital stay (1.533±0.57 versus 2.766±0.567 days, P<0.005) and lower mean hospital expenses (Rupees 1139.99±276.80 compared to 1383.33±284.16, P<0.05). Complete abortion rate was similar between the two groups.

Conclusion: The combined use of Foley's catheter balloon and extra-amniotic PGF2-alpha is more rapid, safe and cost effective method for induction of therapeutic termination of second trimester pregnancy, resulting in greater number of successful uterine evacuation within 24 hours, than the Foley's catheter balloon alone.

Key words: Second trimester, pregnancy termination, Foley's catheter balloon, prostaglandin F2-alpha.

INTRODUCTION

The increasing use of ultrasonography and serological screening has led to early detection of lethal structural and chromosomal abnormalities and intrauterine foetal death[1], which has increased the demand for rapid termination of second trimester pregnancy[1,2]. In the non-intervention policy, the risk of disseminated intravascular coagulopathies is increased if spontaneous expulsion by natural process fails to occur within four weeks of the estimated foetal demise. Psychological problems to the mother may arise after knowing that she is carrying a dead or abnormal foetus in her womb. In such circumstances, termination has to be achieved[3] though abortion rule is not legalized in Pakistan [4].

Termination of pregnancy in the second trimester is very difficult and is associated with 3 to 5 times higher risk of maternal mortality and morbidity than termination during the first trimester[5,6]. The main concern of obstetricians is to provide the most effective and safest regimen, which should have shortest induction to expulsion interval and minimal side effects[4].

Cervix is the main obstacle to empty the uterus, as is evidenced by the various methods advocated to overcome its resistance[2]. Vacuum aspiration is highly effective in first trimester but it needs mechanical dilatation of the cervical canal after 8 weeks onwards[6]. After acute dilatation and evacuation, there is concern about the consequent cervical incompetence and pre-term labour[7]. Cervical dilatation beyond 9 mm has represented tearing of the internal Os rather than dilatation[8]. Dilatation beyond 12 mm did not return to normal patency after 6 weeks of operation[9].

Medical methods are therefore, often preferred for induction and evacuation where

size of the uterus exceeds 12 weeks of gestation; the most common being concentrated oxytocin infusion alone or after initial priming with oestrogen. But it is a prolonged process requiring repeated infusion and is associated with high failure rate[10].

Prostaglandins have been shown to be essential for initiation and normal progress of labour[11]. Synthetic prostaglandins have been used for termination of pregnancy both in early and late second trimester with fewer side effects than the natural prostaglandins[6]. Recently combinations of different procedures and prostaglandins preparations have been used and compared, the main objective being reduction in induction to abortion interval, safety and economy.

PGF2-alpha administered intramuscularly has been proven to be an efficient abortifacient but its systemic use is limited by the undesirable side effects like headache, diarrhoea, vomiting, pain and pyrexia[3,12,13]. Intra-amniotic infusion of 15-methyl-PGF2-alpha has been documented to have shorter induction to products expulsion interval (17.5±8.6 versus 22.3±12.5 hours)[15] and fewer side effects than intra-vaginal mesoprostol or PGE-2 suppositories[14,15]. This route is effective even in the early third trimester[16] and second trimester pregnancy with rupture of membranes[17], but it requires skill.

The most effective medical method for induction and termination of second trimester pregnancy is combination of mifepristone and mesoprostol with reported induction to abortion interval of less than 7 hours[18], but the problem with mifepristone is non-availability and cost of the drug specially in the developing countries.

The use of Foley's catheter balloon alone has shown better results in achieving cervical preparation than the 3 mg dinoprostone vaginal pessary and it is also very economical[2,4,19,20,21]. The mode of action of catheter balloon is postulated to be either by direct mechanical effect or by release of prostaglandins secondary to separation of foetal membranes[19,21]. Combination of double balloon catheter and continuous instillation of extra-ovular PGF2-alpha has resulted in very short mean induction to abortion interval (12.9 and 13.3 hours) and minimal side effects[22,23].

The aim of this study was to compare the combined effect of Foley's catheter balloon and extra-amniotic instillation of PGF2-alpha with the use of extra-amniotic Foley's catheter balloon alone, for its efficacy, safety, frequency of adverse effects and cost effectiveness, so as to select the better one.

MATERIAL AND METHODS

This study was conducted in Obstetrics & Gynaecology Department of Post Graduate Medical Institution, Lady Reading Hospital Peshawar during 2002. Sixty-three women were enrolled in the study, 33 for group-I and 30 for group-II.

Indications for mid trimester abortions were either intrauterine foetal death or lethal structural and chromosomal abnormalities. Subjects were randomly allocated to two Groups, Group-I having odd admission numbers and Group-II having even admission numbers. In Group-I subjects, only extra-amniotic Foley's catheter balloon was used for induction of termination. In Group-II subjects, Foley's catheter balloon was combined with instillation of extra-amniotic PGF2-alpha through the same catheter. Inclusion criteria were: gestational age between 14 to 28 weeks with poor cervical score (less than 4). Exclusion criteria for catheter insertion in both the groups were: foul smelling vaginal discharge, fever, deranged coagulation profile, gestational age less than 14 and more than 28 weeks. Patients having asthma, glaucoma and

cardiovascular diseases were excluded from the use of PGF2-alpha.

All the patients were hospitalised from the time of insertion to evacuation. Before undergoing the trial they were counselled about the use of both the procedures and informed consent was taken. Detailed obstetrics, gynaecological, medical and surgical history was recorded. Detailed general phy-sical examination and pelvic examination was performed to exclude infection and vaginal bleeding, to assess cervical score and ute-rine size.

Essential investigations were performed, including clean catch urine analysis, blood grouping and Rh-factor, blood complete profile, haemoglobin percentage before and after the procedure, coagulation profile including prothrombin time, activated partial thromboplastin time and platelets count. Detailed ultrasonography was performed for gestational age, structural and chromosomal abnormalities of the foetus, intrauterine growth restriction and confirmation of foetal death. Serum uric acid and liver function tests were performed in patients with severe pre-eclampsia and eclampsia.

In both the groups, using sterile techniques, a size 16 French gauge Foley's catheter was inserted through the internal Os, facilitated with a small clamp under direct visualisation with bivalve speculum. The balloon was inflated with 30 millilitres of distilled water; catheter was pulled back and strapped to medial side of the thigh to provide mechanical traction to the balloon. Patients in Group-II in addition received extra-amniotic PGF2-alpha. One millilitre PGF2-alpha injection, containing 5 mgs was diluted in a 20 millilitres disposable syringe with 19 millilitres of normal saline to make 20 millilitres solution (0.25 mg/ml). Two millilitres were instilled through the clamped draining end of the Foley's catheter soon after its insertion and then one millilitre was instilled at hourly interval till expulsion of balloon of the catheter.

Time of insertion and expulsion of Foley's catheter balloon was noted in both the groups. Soon after expulsion of Foley's catheter balloon, pelvic examination was performed to assess the cervical score. Amniotomy was performed and infusion of 30 units syntocinon in one litre Ringer lactate was started at 20 drops per minute, in both the groups, till expulsion of the foetus and placenta either completely or incompletely. Evacuation and curettage was performed under Para-cervical block, when required. Time of expulsion of products and evacuation was noted.

Amount of blood loss was estimated roughly from the soaked pads, bleeding at evacuation and curettage and was assessed from change in the mean values of haemoglobin percentage before and 6 hours after the evacuation.

Pyrexia was noted by keeping 4 hourly temperature records. Events of chills, nausea, vomiting, diarrhoea, headache and pain were noted. Fever was defined as a single rise of temperature more than 100.4°F[15]. All the patients received oral antibiotics, Ampiclox 500mg 6 hourly and Metronidazole 400mg 8 hourly for 7 days.

Data was analysed for mean values of maternal age, parity, gestational age, induction to Foley's catheter balloon expulsion interval, induction to evacuation interval, rate of successful uterine evacuation within 24 hours, incidence of complete abortion, side effects, total hospital stay in days and total hospital expenses. Interviewing the patients after the procedure assessed psychological acceptability of the procedures and symptoms experienced by the patients.

Treatment failure was defined as failure of the patients to expel the balloon within 48 hours after its insertion, where other alternative methods were used for evacuation. They were excluded form calculation of induction to evacuation intervals. The pri-

mary goal was successful uterine evacuation within 24 hours.

Abortion was considered complete if placenta and membranes were delivered within two hours after delivery of the foetus and there was absence of heavy bleeding requiring manual removal of placenta or curettage[15].

For comparison of data Student T-test was used for numerical data and Chi-square test was used for categorical data (%). The result was considered statistically significant with P<0.05 and non significant with P>0.05. Students T-test table and Chi-square x^2 table was used for comparison.

RESULTS

Total 63 women were subjected to the trial; in 33 women termination of pregnancy was induced with Foley's catheter balloon alone (Group-I) while 30 women had induction with the combined use of Foley's catheter balloon and extra-amniotic PGF2-alpha instillation through the same catheter (Group-II).

The demographic characteristics between the two groups were similar. Age of the women ranged from 18-39 years and parity ranged from 0-10 in both the groups. The mean values of maternal age, parity and gravidity were statistically not different in both the groups (P > 0.05), as shown in Table-1.

Gestational age ranged from 14-28 weeks by dates and 14-26 weeks by ultrasonography in both the groups. Mean gestation age had no significant difference between the two groups both by dates (19.45±3.509 versus 20.43±3.635 weeks) and by ultrasonography (17.64±2.77 versus 18.16±3.695 weeks, P>0.05).

Indications for termination were similar between the two groups. Majority of patients had termination for intra-uterine foetal death, 30 in group-I (90.9%) and 26 in group-II (86.66%). Patients in Group-I had one severe hydrops-foetalis (3.03%) and two anencephalic foetuses (6.06%) while patients in Group-II had one hydrops-foetalis (3.33%) and three anencephalic foetuses (9.99%).

As is evident from Table-2, the mean induction to Foley's catheter balloon expulsion interval was significantly shorter in group-II patients than group-I (13.216±8.629 versus 33.88±11.345 hours, P<0.005). Similarly the mean induction to products expulsion interval was shorter by 21.26 hours in

CHARACTERISTICS OF THE PATIENTS

Total patients:
Group-I = 33
Group-II = 30

Characteristics	Group-I	Group-II	T-cal
Mean maternal age	27.42±6.082	27.96±6.543	-0.338 NS
Mean parity	2.49±2.487	3.00±2.212	-0.357 NS
Mean gravidity	4.18±3.015	4.93±2.765	-1.030 NS
Mean gestational age			
A)–by dates	19.45±3.509	20.43±3.635	-1.086 NS
B)–by ultrasonography	17.64±2.77	18.16±3.695	-0.627 NS

NS=non significant P> 0.05 T-cal = T value calculated by student T-test Mean±SD=Standard Deviation
T-value from table at column 0.05 for 60 degree of freedom is 1.671

TABLE – 1

MEAN INDUCTION TO PRODUCTS EXPULSION INTERVAL IN HOURS

Total patients:
Group-I = 33
Group-II = 30

Variable	Induction to balloon expulsion	Balloon expulsion to products expulsion	Induction to products expulsion
Group-I	33.88±11.345	3.88±4.708	37.76±11.019
Group-II	13.216±8.629	3.25±3.483	16.50±8.823
Difference	20.664	0.63	21.26
T-calculated	7.941	0.589	8.249
P-value	P<0.005(HS)	P>0.05 (NS)	P<0.005(HS)

T-value from T-distribution table for 60 degree of freedom in column 0.05 is 1.671 and in column 0.005 = 2.660

> = More than < = less than HS = Highly Significant NS = Non Significant

TABLE – 2

Group-II patients than Group-I (16.50±8.823 versus 37.76±11.019 hours), which is statistically a highly significant difference (P<0.005). But the mean interval from Foley's balloon expulsion to products expulsion did not differ significantly between the two groups (P>0.05).

Table-3a shows that Foley's catheter balloon was expelled within 24 hours by 28 (93.33%) patients in the combined use of Foley's catheter balloon and PGF2-alpha group compared to only 10 (33.33%) patients in the Foley's catheter balloon alone group (P<0.01). Seventeen (56.67%) patients in Group-II expelled the balloon in less than 12 hours compared to none in Group-I (highly significant P<0.01).

As indicated in Table-3b, a significantly greater number of patients in group-II reached the main outcome goal of successful uterine evacuation within 24 hours than group-I (86.66% versus 6.06%, P<0.01) and most of the patients (93.33%) expelled the products in less than 36 hours in group-II, compared to only 33.33% in group-I (P<0.01).

MEAN INDUCTION TO FOLEY'S CATHETER BALLOON EXPULSION INTERVAL (HOURS DISTRIBUTION)

Total patients:
Group-I = 33
Group-II = 30

Interval range in hrs	Group-I		Group-II	
	No of pts	%	No of pts	%
< 12	0	0	17	56.67
12 to < 24	10	30.303	11	36.67
24 to < 36	4	12.121	1	3.33
36 to < 48	16	48.484	1	3.33
48 to > 48 (Procedure failure)	3	9.090	0	0
Total	33	100.00	30	100.00

TABLE – 3a

MEAN INDUCTION TO PRODUCTS EXPULSION INTERVAL (HOURS DISTRIBUTION)

Interval range in hrs	Group-I			Group-II		
	No of pts	%	P	No of pts	%	P
< 12	0	0		8	26.66	HS
12 to < 24	2	6.06		18	60.00	HS
24 to < 36	9	27.272	HS	2	6.67	
36 to < 48	19	57.575	HS	2	6.67	
48 to > 48	3	9.09	NS	0	0	
Total	33	100.00		30	100.00	

< = Less than % = percentage No= Number HS = Highly Significant P<0.01
> = More than pts = Patients hrs=hours NS = Non Significant P>0.05

TABLE – 3b

The 48 hours expulsion rate was not different between the two groups. In group-II all the patients expelled the products within 48 hours while in group-I three patients (9.09%) did not expel Foley's catheter balloon and the products within 48 hours (non significant P>0.05). They were considered as treatment failure and were excluded from calculation of induction to products expulsion intervals.

The rate of complete abortion was similar between the two groups, 26 cases (72.27%) in group-I and 23 (76.66%) in group-II (P>0.05).

Parity had no significant effect on mean values of induction to Foley's balloon expulsion interval and induction to products expulsion interval in both the groups (P>0.05), as shown in Table-4.

Complications rate: The side effects in group-II patients due to PGF2-alpha were minimal. Only 3 patients (10%) complained of nausea and vomiting, 2 (6.66%) had diarrhoea and 3 (10%) had cramping uterine pain requiring tramadol injection for pain relief, compared to one patient (0.03%) having vomiting, one (0.03%) having pain and none with diarrhoea in Group-I, which is not significant (P>0.05). Only one patient in group-I had 101°F spike of temperature on two occasions but this was one of the

EFFECT OF PARITY ON THE RESULT

Group-I: Nullipara = 10 Multipara = 20
Group-II: Nullipara = 6 Multipara = 24

Mean interval in hours	Parity	Group-I	Group-II
Induction to Foley's balloon expulsion	Nullipara	31.8±12.96	14.66±9.786
	Multipara	34.87±10.584	12.85±8.52
T-calculated		- 0.648 NS	0.415 NS
Induction to products expulsion	Nullipara	35.8±11.395	16.83±10.419
	Multipara	38.75±10.964	16.417±8.578
T-calculated		- 0.676 NS	0.089 NS

T-tab = 1.701 at 28 degree of freedom in column 0.05 NS=non significant P>0.05
T-tab = value from T-distribution table of student's T-test

TABLE – 4

AVERAGE HAEMOGLOBIN DEFICIT IN GRAMS PER DECILITRE (g/dl)

Total patients:
Group-I = 33
Group-II = 30

Variable	Pre-op.	Post-op.	Difference	T-cal
Group-I	11.865±1.308	11.39±1.289	0.475	1.417(P>0.05)
Group-II	11.22±1.11	10.92±1.053	0.30	1.076 (P>0.05)

TABLE – 5

AVERAGE HOSPITAL STAY IN DAYS & EXPENSES IN RUPEES

Variable	Group-I	Group-II	Difference	T-cal.
Avg. hospital stay	2.766±0.567	1.533±0.57	1.223	8.404 (P<0.005)
Avg. hospital expenses	1383.33±284.16	1139.99±276.80	243.34	3.359 (P<0.05)

Pre-op = Pre-operative Avg = Average < = less than T-cal = calculated T-value by
Post-op = Post operative > = more than student's T-test

TABLE–6

treatment failure cases. A significant number of patients (8/33=23.64%) in group-I had temperature spikes of 100°F on one occasion compared to only one patient (3.33%) in group-II (P<0.05).

Bleeding was moderate in amount needing no blood transfusion. The average haemoglobin deficit after expulsion of products was 0.475 g/dl in group-I patients and 0.30 g/dl in group-II, which is statistically non-significant (P>0.05, Table-5). Only one patient in group-II and three in group-I needed blood transfusion before insertion of Foley's catheter because of their low haemoglobin levels on admission.

The average expenses of one-day hospital stay were rupees 500, while one ampoule of PGF2-alpha had cost only rupees 350. Only two patients (6.66%) in group-II required two ampoules of PGF2-alpha, while 28 patients (93.44%) needed only one ampoule, making the average per patient cost of PGF2-alpha 373.33 rupees. As indicated in Table-6, group-I patients had to stay in the hospital for significantly longer duration than group-II (2.766±0.567 versus 1.533±0.57 days, P<0.005). This prolonged hospital stay raised the average hospital expenses of group-1 patients by 243.34 rupees more than group-II (P<0.05), making the combined use of Foley's catheter balloon and extra-amniotic PGF2-alpha a more rapid and cost effective procedure.

DISCUSSION

The superiority of Foley's catheter balloon for cervical ripening in second trimester termination of pregnancy has been documented in different studies[2,4,24,25].

The efficacy and safety of the combined use of balloon catheter and extra-amniotic instillation of PGF2-alpha has been studied with favourable results[22,23], but studies comparing the combined use of Foley's catheter balloon and extra-amniotic instillation of PGF2-alpha with the use of extra-amniotic Foley's catheter balloon alone are limited. We have found only one such study through 10 years literature review on Med-Line and Pub-Med.

In this study we wanted to see whether the combined use of extra-amniotic PGF2-alpha and Foley's catheter balloon would augment the process of termination. We found that the mean induction to Foley's balloon expulsion interval was considerably shorter with the combined use of Foley's catheter balloon and extra-amniotic PGF2-alpha (group-II) compared to the use of Foley's catheter balloon alone (group-I), 13.216±8.629 versus 33.88±11.345 hours (P<0.005). Similarly the mean induction to foetus expulsion interval was shorter by 21.26 hours in group-II compared to group-I (16.50±8.823 versus 37.76±11.019 hours), which is statistically a highly significant difference (P<0.005).

In the study conducted by Tasleem A et al[3] the mean values of induction to Foley's balloon expulsion interval (13.17±4.37 hours) and induction to products expulsion interval (16.67±6.71 hours) with the combined use of Foley's catheter balloon and extra-amniotic PGF2-alpha were similar to our result (13.21±8.62 & 16.50±8.82 hours respectively). But the mean values of induction to Foley's balloon expulsion interval (16.45±4.99 hours) and induction to products expulsion interval (19.95±5.56 hours) with the use of Foley's catheter balloon alone, in contrary to our study, were much shorter, making the difference in the intervals between the two groups in their study, statistically non-significant (P>0.05). The mean interval between Foley's bulb expulsion and products expulsion in their study was 3.5 hours in both the groups, which is comparable to our study (3.88±4.708 hours in group-1 versus 3.25±3.483 hours in group-II) and the difference is statistically non-significant (P>0.05).

In the study conducted by Pushpa Sirichand S, the mean induction to abortion interval with Foley's catheter balloon was 26.3±8.2 hours, which is more closer to our result in group-I (37.76±11.019 hours)[4].

The mean induction to delivery intervals of 12.3±6.4 hour[14] and 17.5±8.6 hours[15] shown with the use of intra-amniotic injection of PGF2-alpha and 13.3 hours with the use of continuous extra-ovular instillation through balloon catheter,[23] are comparable to our study (16.50±8.823 hours) with the combined use of Foley's catheter balloon and extra-amniotic PGF2-alpha. They have also reported minimal side effects of nausea, vomiting, diarrhoea, pyrexia and uterine cramps, similar to our study.

The study of Tasleem A et al[3] also does not agree to our study in respect of cost effectiveness of the combined use of PGF2-alpha. But in our study the average hospital stay required by the patients in group-I was 1.223 days longer than group-II (2.766±0.567 versus 1.533±0.57 days, P<0.005), which raised their average hospital expenses by 243.34 rupees more (1383.33±284.16 rupees compared to 1139.99±276.80). The difference reached statistical significance (P<0.05), making the combined use of extra-amniotic PGF2-alpha and Foley's catheter balloon more cost effective. In addition the psychological tension of the patient and their attendants awaiting termination of unwanted pregnancy for prolonged hours was considerably reduced in group-II patients.

Complete abortion rate was similar between the two groups, 72.27% in group-I compared to 76.66% in group-II (P>0.05). Successful termination rate within 24 hours of 86.66% (P<0.005) in our study was consistent with the 88% achieved with intra-amniotic injection of 15-methyl-PGF2-alpha[15]and 96% with the use of continuous extra-ovular instillation of PGF2-alpha through double balloon catheter[22]. Successful termination rate within 24 hours was much less (6.06%) in the Foley's catheter only group while within 36 hours it was 93.33% in group-II and 33.33% in group-I. So this simple procedure of combination of Foley's catheter balloon and extra-amniotic PGF2-

alpha can replace these skilful and costly procedures.

The average blood loss evident from the haemoglobin deficit after products expulsion was minimal (P>0.05) in both the groups (0.475 g/dl in group-I versus 0.30 g/dl in group-II), which is comparable to other studies[3,15].

The frequency of pyrexia, in contrast to other studies[3,4], was significantly higher in the Foley's catheter balloon alone group, (23.64% compared to 3.33% in group-II, P<0.05) probably because of the prolonged induction to abortion interval.

CONCLUSION

No method is ideal without unwanted side effects but the combined use of Foley's catheter balloon and extra-amniotic instillation of PGF2-alpha is more efficacious than the Foley's catheter balloon alone. It is cost effective in terms of shortening the duration of hospital stay, saving the patient's and attendant's time and their hospital expenses by causing rapid termination. It is associated with negligible side effects, is well tolerated and more acceptable to the patients. Blood loss is moderate in amount needing no blood transfusion. The procedure does not require more skill so its use is strongly recommended at least in the areas where injectable PGF2-alpha is easily available and properly cold stored.

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