



Original Article

Does tubal sterilization affect menstrual bleeding pattern?

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Abstract

Objectives: Current contraceptive prevalence in Kerala is 64 percent and tubal sterilization (TS) dominates the methods mix, 76 percent. Many recent researches have reported an association between tubal sterilization and abnormal menstrual bleeding pattern. Hence the objective of this study was to analyze the menstrual diary data to look into the association of tubal sterilization with menstrual bleeding pattern and dysmenorrhea. **Methods:** A prospective cohort of 480 TS acceptors and 155 non-acceptors selected from a community were followed up over a period of 18 months to compare menstrual diary data, clinical and laboratory findings. Menstrual diary was analyzed by reference period method. We used multivariate logistic regression to identify independent predictors. **Results:** Among the sterilized women, 71% had acceptable menstrual pattern whereas in the control group this was 73%. Reduced/infrequent pattern was estimated in 21%, frequent/prolonged bleeding in 12% and dysmenorrhea in 24%. In the control group, respective percentage of the above three conditions were 16, 13 and 20. In multivariate analysis, unacceptable menstrual bleeding pattern and dysmenorrhea were not statistically significant amid the two groups. Lower reproductive tract infections and menstrual hygiene were identified as independent predictors for unacceptable menstrual bleeding. The risk for dysmenorrhea is high by minilaparotomy procedure. **Conclusion:** Tubal sterilization is safe, as it involves no augmented risk for unacceptable bleeding pattern, and cycle related pain. Early treatment of reproductive tract infections and health education to improve menstrual hygiene are of prime importance to reduce menstrual morbidities.

Key words: tubal sterilization, frequent/prolonged bleeding, reduced/infrequent bleeding, acceptable bleeding pattern, dysmenorrhea.

Introduction

Currently, Kerala has a high contraceptive prevalence and is at 64 percent among the currently married women in the age 15-49 years. Tubal sterilization (TS) dominates the contraceptive methods mix accounting

for 76 percent of the current contraceptive prevalence¹. Presently adopted TS procedures include minilaparotomy, laparoscopic sterilization and Post Partum Sterilization (PPS), i.e., within 6 weeks of delivery. The procedure can be done either during interval period or as post abortion / post partum procedure. Recent researches have given away two outlooks (an augmented risk or no risk) on the association between menstrual bleeding patterns and TS.

Abnormalities related to menstruation could be reduced/infrequent, frequent/prolonged or no cyclical bleeding. Frequent/prolonged bleeding can jeopardize the physical health status of women due to increased blood

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loss. Reduced/infrequent or no bleeding often get a propensity to be categorized as “simple nuisance” side effects, but the clinical significance of this should not be underestimated. It impinges on the sexual, cultural and religious practices², upsets the emotional response and negatively impact the health and quality of life of the women.

Studies, which raised concern, had shown that there is added number of hospitalizations for menstrual related problems among women who had undergone TS and a possible biological effect could not be ruled out. Abnormal bleeding patterns and pelvic pains are the major troubles consequent to sterilization³. Excess numbers of hysterectomy among the sterilized women were performed either for abnormal bleeding pattern or pelvic pain^{3,4}. Abnormal bleeding pattern may either be excessive bleeding, spotting, prolonged bleeding and increased pain during menses^{5,6}. The preliminary findings of CDC, British record linkage study further strengthens these associations. A large case controlled study in Scotland had revealed higher than expected levels of hysterectomy among the sterilized; the risk being four times higher. Women who had adopted sterilization as post partum procedure have less chance for hysterectomy than interval⁷. Other characteristics that could contribute for menstrual related problems among women are, the younger age at which women get sterilized; increasing years following sterilization, shorter the gap between the last childbirth and sterilization and the status of past contraception^{3,5,8,9}.

The concern with control group was a setback in many studies on sterilization and its impact. A large prospective British study, a second CDC report and a major study undertaken by US Collaborative Review of Sterilization (CREST) with a control group, report that women who had undergone sterilization are no more likely than other women to have menstrual abnormalities^{10,11}. The US study revealed no persistent changes in menstrual bleeding pattern or length of cycle among the sterilized women. Rather, they are prone to reduced bleeding and irregular cycles¹².

Tubal sterilization is the most popular contraception in the state of Kerala with reported controversy over risk. This necessitates a look into the effect of tubal sterilization and menstrual bleeding pattern. Menstrual cycle data are often collected from women as self report symptoms and dependability on self reported symptoms are doubtful. A prospective analysis of

menstrual cycle pattern by a monthly menstrual diary will be highly reliable¹³.

Thus, this study was undertaken with the following objectives.

1. To analyze the menstrual diary data to see the association of tubal sterilization on menstrual bleeding pattern and cycle related pain (dysmenorrhea).
2. To see, how menstrual bleeding pattern and dysmenorrhea are affected by a) procedures of sterilization, b) duration of sterilization, c) place of sterilization and d) obstetric status at tubal sterilization.

Methods

Minimum sample size required with a 20% prevalence of menstrual related problems among non-acceptors of sterilization and 45% among sterilized women with $\alpha=0.05$ (two tailed) and $\beta=0.10$ were 72 cases from each group¹⁴. The sample size for sterilization acceptors was increased 3 times (216 cases), to study the effect of four variables pertinent to sterilization.

The total population of selected panchayat (local administrative block) for study, which has 11 wards, was enumerated. The enumerated population was 30622, which included an eligible group (women in age group of 20-40 years) of 6062 women. From this eligible group, 2800 women were selected using computer generated random numbers. With a structured interview schedule, we could recruit 635 women as study cohort, who had satisfied the inclusion criteria. Those women were considered eligible in the age group of 20-40 years, currently married, living with the spouse and had at least one full term pregnancy and childbirth. Additional key criteria being that they were either acceptors of female sterilization in the last 10 year period from August 1990 to August 2000 or non-users of any modern contraception in the last one year period. Those who practiced natural methods or rhythm method were not excluded from non-user status. The study was executed after the ethical review of the protocol by an independent committee.

Three sets of data were collected from this study cohort at six monthly intervals. The first and third sets of data were collected as house visit, while the second data collection was done in the clinic where they were requested to report for examination. During the first

house visit, a menstrual diary was given, to the patients to keep a calendar of menstrual cycles and the women were trained to chart the menstrual bleeding pattern and related conditions. Information was collected using a structured interview schedule on other independent study variables (Box 1).

Insert Box 1. Independent variables selected for the study

Six months after recruitment, the women were subjected to per speculum (PS) examination with informed consent, and bimanual pelvic examination (PV) examination. The aim was to detect any evidence for organic diseases and lower Reproductive Tract Infections (RTI). To evaluate lower RTI, specimens collected included vaginal and cervical discharge. Cervical specimens were collected after wiping vaginal tract three times with sterile cotton. Organism tested were Monilia and Trichomonas Vaginalis infection (wet film examination with KOH and NaCl) Bacterial vaginosis¹⁵ (Nugent's score >4-7, & >7), Gonococcus and other gram positive and negative organisms (Gram stains & culture and sensitivity). Necessary medicines were either given or prescribed and cases requiring reference were advised on that. Those who did not attend the clinic were met at their residence to collect information on reported morbidity conditions and reasons for not attending the clinic. Menstrual diary markings were verified in second follow up and necessary clarifications were made. During the third visit, the menstrual diary was verified and collected back.

Monthly Menstrual Diary Analysis: The information that could be collected from the menstrual diary included, 1. Frequent/prolonged bleeding, 2. Reduced/infrequent bleeding, 3. Acceptable/normal bleeding pattern, 4. Painful menses (dysmenorrhea), 5. Discharge + Itching and 6. Other diseases.

Menstrual bleeding pattern from the menstrual diary were analyzed by a reference period method suggested by Rodriguez et al¹⁶. The menstrual diary was divided into reference period of 90 days, starting from the first bleeding episode after enrolling for the study. For each subject, the indicators of vaginal bleeding pattern considered for each reference period were,

- 1) Number of bleeding days i.e. number of times the women start bleeding in a reference period.
- 2) Total bleeding days in a reference period.
- 3) Longest bleeding run.

- 4) Average episode length measured as the sum of average bleeding run and average non-bleeding interval.

Based on the above indicators, the important categories of clinically significant bleeding pattern developed by ICMR task force study was adopted in this study to analyze the menstrual diary¹⁷. The criteria for these categories were,

1. Frequent/prolonged bleeding: If the subject has either of the following
 1. Bleeding runs ≥ 5
 2. Average episode length =21 days
 3. Total bleeding days > 20 days
 4. Longest bleeding run > 10 days
2. Reduced/infrequent bleeding: If the subject has none of the above, but has either of the following,
 1. Bleeding runs 0-1
 2. Average episode length > 35 days
 3. Total bleeding days ≤ 5 days
3. Acceptable/normal bleeding pattern, If the subject has none of the above.

All the indicators were tabulated for each reference period for all subjects who had kept a menstrual diary. The diary was considered adequate and used in analysis if it held information for a minimum of ≥ 6 month's period. Diary with less than 6 months menstrual cycle information or incomplete and those who could not keep menstrual diary were excluded from menstrual diary analysis.

Results

The sample size was 635 currently married women in the age group of 20-40 years. This included 480 female sterilization acceptors in the last 10 year period from August 1990 to August 2000, and 155 women who were non-users of any modern methods of contraception in the past one year period. Out of this sample, 59% of women were able to keep up menstrual diary that contained minimum of 6 months data. The split of this included 80 nonusers of contraception and 292 sterilization acceptors (Table 1).

The group of women, who were able to keep a menstrual diary and those who were not able to keep the diary, did not differ significantly in their baseline characteristics. Thus table 2 shows the baseline characteristics of the women who were able to keep the

Table 1. Sample distribution of study population.

	Total	Sterilization	Non acceptors
Sample population	635	480 (75.6)	155 (24.4)
Menstrual diary	372 (58.6%)	292 (78.5)	80 (21.5)

Table 2. Characteristics of women who could keep menstrual diary (n=372).

Socio-economic characteristics	Frequency (%) / Mean	Demographic characteristics	Frequency (%) / Mean
Caste		Total no pregnancies	
Hindu	77.9	1	12.8
Muslims	13.4	2	55.0
Christians	8.7	>=3	32.2
Residence		Mean no pregnancy	
Urban	3.5	Acceptors	2.5
Rural	96.5	Non acceptors	1.6
Job women		Age group	
Coolie	2.5	20-24	8.2
Office/School	1.4	25-29	32.5
Professional	0.3	30.34	31.1
House wife	95.9	35-40	28.1
Economic Status – Lower	28.9	Type of sterilization	
Middle	69.5	PPS	76.4
Upper	1.6	Minilap	8.0
Education illiterate	1.1	Laparoscopy	15.6
Read & write	1.6	Place of sterilization	
Lower school	6.8	Govt. hospitals	12.2
Middle school	11.7	Camp	9.0
Upper school	59.7	Medical college	68.8
College	19.1	Private hospitals	10.1
Average age-Acceptors	31.9	Obstetric status at sterilization	
Non acceptors	28.7	Concurrent with MTP	1.0
Average age-Menarche	13.9	LSCS	9.0
Acceptors	13.9	Post natal	70.5
Non acceptors	14.1	Interval	19.4
Average BMI		Previous contraceptive use	
<18.6	66.5	No	86.6
18.7-23.8	30.5	IUD	11.4
>23.9	3.0	Condom	1.4
Presence of other disease		Oral pills	0.5
No	90.2	Mean LCB (duration in months)	
Yes	9.8	Acceptors	68.2
Menstrual hygiene		Nonacceptors	44.5
Inadequate	40.6	No Still birth	
Adequate	59.4	No	99.7
Lab RTI Acceptors	43.9	>=1	0.3
Non acceptors	42.6	No. of abortions	
Sterilization duration <=5 yrs	47.2	No	86.1
>5 yrs	52.8	>=1	13.9
		No. of MTP	
		No	92.1
		>=1	7.9
		No of CS	
		No	90.2
		>=1	9.8
		Current lactating	
		No	93.2
		Yes	6.8

menstrual diary that had a minimum of 6 months information.

Ninety six percent of the studied sample was housewives, 70% of which belonged to middle economic status and nearly 80% of it had upper school or college education. Mean age of non-acceptors was 29 and that of sterilized women was 32 years; corresponding parity was 1.6 and 2.5 respectively. Nearly 53% had undergone sterilization between 5-10 years and the rest 47% within the last 5 years. Ten percent of the women had a minimum of at least one caesarean section (CS) in the past, 8% had at least one Medical Termination of Pregnancy (MTP) and 14% had spontaneous abortion. With a predefined classification, 59% had adequate menstrual hygiene practices, and 87% had no past history of contraceptive use. Nearly 43% of the population had laboratory diagnosed lower reproductive tract infections, which included either monilial, trichomonas vaginalis or bacterial vaginosis (Nugent's score > 4). Sixty nine percent of the women had adopted sterilization from medical college, 12% from government hospitals other than medical colleges, 9% from temporary camp setting and 10% from private hospitals. Further, 76% and 6% had adopted sterilization as post partum sterilization (PPS) or as laparoscopic procedure respectively. Seventy one percent had undergone sterilization within six weeks after delivery and 19%, during the interval period. Less than average (<18.6) Body Mass Index (BMI) was measured with 67% whereas 10% of the sample had reported for the presence of other diseases.

Menstrual Diary Analysis: Table III shows the prevalence of menstrual cycle related problems. Among the 372 subjects, who could keep menstrual diary, 71% had an acceptable menstrual pattern, 12% had frequent/prolonged bleeding and 20% had reduced/infrequent pattern. Dysmenorrhea was charted by 23%.

In order to see whether the two groups (those who could keep a menstrual diary and those without menstrual diary, were different in morbidity pattern), the self reported morbidity collected in three visits in these two groups was compared, but did not show any statistical significance. Sixteen subjects, who included, 11 sterilization acceptors and 5 non-users were lost to follow up.

Bivariate analyses with chi-square test for statistical significance were done to see the difference among acceptors and non-acceptors in menstrual bleeding pattern, and dysmenorrhea (Table III). There were no statistically significant differences for menstrual bleeding pattern among non-acceptors and acceptors. The reduced/infrequent patterns by menstrual diary were high (21%) among the sterilized, when compared with the non-acceptors (16%), but the difference was not statistically significant. Acceptable menstrual pattern were there with 70% of sterilized and 73% of non sterilized women. Eleven percent of the sterilized and 13% of the non-acceptors reported frequent/prolonged bleeding pattern. Dysmenorrhea was not statistically significant in the two study groups, being 24% in sterilization acceptors and 20% among non acceptors of sterilization.

Table 3. Prevalence and cross-tabulation of menstrual bleeding pattern.

Categories	Prevalence of Menstrual problems (%)	Menstrual diary	chi-square P value
Acceptable pattern	70.7 (263/372)		
Acceptors %		70.2 (205/292)	.690
Non Acceptors %		72.5 (58/80)	
Frequent/prolonged	11.6 (43/372)		
Acceptors %		11.3 (33/292)	.766
Nonacceptors %		12.5 (10/80)	
Reduced/infrequent	19.6 (73/372)		
Acceptors %		20.5 (60/292)	.391
Nonacceptors %		16.3 (13/80)	
Dysmenorrhea	23.4 (87/372)		
Acceptors %		24.3 (71/292)	.419
Nonacceptors %		20.0 (16/80)	

Does tubal sterilization affect menstrual bleeding pattern ?

The menstrual bleeding pattern and dysmenorrhea were not significantly different among acceptors and non-acceptors of sterilization. Bivariate analyses of other independent predictors were carried out separately to identify the risk factors for abnormal menstrual bleeding pattern and dysmenorrhea. Independent predictors shown in box 1 were used for analysis with each dependant variable. Clinic was attended by 53.2% (198/372) of the women who could keep diary.

Table IV shows the three categories of bleeding pattern (dependant variable) with the independent variable that became chi-square significant in bivariate analysis. Other independent variables that did not show evidence of significance are not shown. Among the women with no infection of the lower tract with monilia, 67% reported an acceptable pattern, whereas in the case of those

with monilial infection, only 51% had acceptable pattern. The chances to have acceptable pattern is reduced by 50% if the women have monilial infection of lower reproductive tract. Reduced/infrequent bleeding pattern were significantly associated with monilial infection. Among the women with laboratory diagnosed monilial infection, 35% had reduced/infrequent bleeding pattern, whereas this was seen in only 21% of the women with no monilial infection. The relative risk was 2.2.

Bivariate analysis of frequent/prolonged bleeding pattern was statistically associated with menstrual hygiene practices. In those with inadequate menstrual hygiene, 18% have reported frequent/prolonged bleeding, whereas this was present in only 8% with adequate hygiene practices. The risk is reduced to 60% if menstrual hygiene is adequate.

Table 4. Bivariate analysis of menstrual bleeding pattern with statistically significant independent predictors.

Variables	Acceptable	Reduced/infrequent	Frequent/prolonged
Monilia* No	67.1% (104/155)	20.6% (32/155)	
Yes	51.2% (22/43)	34.9% (15/43)	
	P<0.5; RR-0.514 CI-.259-1.020	P<0.05; RR 2.2 OR-.984-4.307	
Menstrual hygiene			17.6% (26/148)
Inadequate			7.6 (17/224)
Adequate			P<0.003-0.385 OR-.201-.739

· Out of the 372 cases who could keep menstrual diary, 198 cases reported to clinic for examination.

Bivariate analysis of dysmenorrhea that could be identified by menstrual diary verification was significantly associated (Table V) with the procedure of TS, the place of TS, the obstetric status at TS and the use of past contraception. Dysmenorrhea was reported by 46% of the women with minilaparotomy as TS procedure, 22% with PPS and 25% with laparoscopy procedure. Women who had done sterilization from all other government hospitals excluding medical colleges and from the camp setting reported 39% and 32% dysmenorrhea whereas those who had sterilization from medical college and private hospitals reported 23% and 10% respectively. Dysmenorrhea report was high for those who accepted sterilization concurrent with MTP (100%) and low for those with interval acceptance (30%). Thirty six percent of the past contraceptive users

reported dysmenorrhea but this number was only 21% among those with no past contraceptive use (RR=2).

Result of Multivariate Analysis

The independent variables entered in multivariate analysis for each category of menstrual bleeding pattern were all those variables that were significant in bivariate analysis with few other variables that have the possibility of affecting menstrual bleeding pattern. The independent variables considered are acceptors or non-acceptors of sterilization, lower reproductive tract infections with monilia or bacterial vaginosis, menstrual hygiene, blood hemogram level less than 10 gm, age and parity of the women, body mass index and presence of other diseases. Multivariate analysis (Table VI) of acceptable pattern had shown that for those with

Table 5. Bivariate analysis of dysmenorrhea with independent variables (significant predictors alone tabulated).

Variables	Dysmenorrhea	Variables	Dysmenorrhea
Sterilization place		Past contraception use	
Govt. hospitals	38.9% (14/36)	No	21.4% (69/322)
Camp	32.0% (8/25)	Yes	36.0 (18/50)
Medical college	22.9% (46/201)		sig. - .024
Private hospitals	10.0% (3/30)		RR 2.063
	sig. - .036		CI;1.092 3.895
Procedure		Obstetric status MTP	100.0% (3/3)
PPS	21.9% (49/224)	LSCS	13.8% (4/29)
Minilap	45.8% (11/24)	Post natal	23.0% (47/204)
Laparoscopy	25.0% (11/44)	Interval	30.4% (17/56)
	sig. - .034		sig. - .006

monilia infection, the chances to have an acceptable bleeding pattern were reduced to 50%. Women with monilia infection have three times increased risk for

development of reduced/infrequent bleeding pattern. The chance for frequent/prolonged bleeding pattern is two third less in those with adequate menstrual hygiene.

Table 6. Multivariate analysis of menstrual bleeding pattern and dysmenorrhea.

Variable	Odds Ratio Reference	Reduced/ infrequent	Frequent/ prolonged	Acceptable	Dysmenorrhea*
Monilia (YES)	No	sig. .020 OR 3.275 CI 1.201-8.929		sig. 0.048 OR 0.496 CI 0.247-0.995	
Menstrual Hygiene (Adequate)	Inadequate	sig. .013 OR .355 CI 0.156 – 0.805			
Obstetrics Status Concurrent Caesarean	MTP Post natal Interval				sig 0.041 OR – 0.109 CI .013 – 0.917
Minilaparotomy	PPS Laparoscopy				sig. 0.046 OR – 2.674 CI 1.016-7.041

The independent variables entered are 1) acceptors or non acceptors of sterilization, 2) Lower reproductive tract infections with monilia or bacterial vaginosis, 3) Menstrual hygiene, 4) Blood hemogram level < & > 10 gm, 5) Age, 6) Parity of the women, 7) Body mass index and 8) presence of other diseases.

*1) Place of sterilization, 2) Procedure, 3) Past contraception uses, 4) Obstetric status at sterilization, 5) acceptors or non acceptors of sterilization.

The independent variables entered are 1) acceptors or non acceptors of sterilization, 2) lower reproductive tract infections with monilia or bacterial vaginosis, 3) menstrual hygiene, 4) blood hemogram level < & > 10 gm 5) Age, 6) Parity of the women, 7) Body mass index and 8) Presence of other diseases.

Dysmenorrhea is associated with three times higher risk in women who had accepted sterilization as

minilaparotomy procedure and 90% reduced risk when sterilization was done simultaneous with cesarean section.

Box 1. Independent variables selected for the study.

General health status of the women	Place of sterilization
Blood Hb (<10, >=10 & <11, >=11) Urine routine	Government hospitals other than medical colleges,
BMI, (<18.5, 18.5-23.8 & >23.9)	Temporary camps set up
Blood pressure etc.	Medical colleges and
Residence	Private hospitals
Caste	Type of procedure
Educational status	Laparoscopy
*Economic status	PPS or
Age & parity	Minilaparotomy
Past history of abortion,	Obstetrics status at sterilization
Medical Termination of Pregnancy (MTP),	Post partum
Still-births	Post abortion/MTP/or
Caesarean section (CS)	Interval
Past use status of contraceptives	Duration of sterilization (=60, >60 months).
*Menstrual and other hygiene practices	
Reproductive tract infections	

*Using a predefined classification menstrual hygiene practice and economic status were assessed. Menstrual hygiene practices were score considering material used as pad or clothes, number of times clothes reused and cleaning like sun drying etc., number of times pads changed per day. Economic status was assessed after assigning points. The three categories were upper (>20 points), middle (10-20) and lower class (<10 points). The points were assigned depending on the type of house they live, including roof, floor and number of rooms, owning they have (like TV & VCR, fridge, radio, vehicles etc.), land ownership, income they earn and also by subjective assessment at the time of house visit.

Discussion

The present study strengthens the fact that tubal sterilization is safe as it has no augmented risk by way of variation in menstrual bleeding pattern and dysmenorrhea. The probability for reduced/infrequent bleeding pattern, though not statistically significant, was elevated in those who accepted sterilization in contrast to non-acceptors. The biological significance of these symptoms should not be underestimated, and further studies are indispensable to elicit the patho-

physiological and biochemical effects of ovarian function subsequent to tubal sterilization. This result supports the report by Peterson et al., where they could not find the association of menstrual bleeding pattern with TS and the possibility of reduced bleeding pattern was high with tubal sterilization¹².

Risk factors analysis had revealed that in monial infection of lower genital tract, there is a three times elevated risk for reduced/infrequent bleeding pattern and the likelihood to have acceptable menstrual

bleeding is reduced by 50%. With adequate menstrual hygienic practices, the chance for frequent/prolonged bleeding pattern was reduced by 60%. As we could not refer a possible biological effect to prove these findings with the present existing knowledge, further studies are needed in this regard.

Dysmenorrhea is more when sterilization was done as minilaparotomy procedure than when compared with laparoscopy and post partum sterilization. The tissue disruption at the time of operation and subsequent adhesion could possibly be a contributing factor. In the other two procedures the tissue destruction could possibly be low. There is the possibility for reduction in dysmenorrhea when sterilization was done concurrent with caesarean section.

From this study it was evident that, irrespective of whether the women are sterilized or not, 30% of the studied population had unacceptable bleeding pattern. Prevalence of dysmenorrhea was 20%. Even though these findings are not directly applicable to our study, it should not be neglected because this causes significant morbidity for women in the reproductive age group.

Counseling before sterilization should be emphasized as sterilization is not the cause for either menstrual problems or dysmenorrhea. Early detection and treatment of RTI should be given prime importance and health education stressing the need for improving menstrual hygienic practices is necessary for reducing menstrual morbidity. Menstrual problems either debilitating the general health condition of the women or as nuisance side effects should get prompt attention to improve the reproductive health status of women.

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