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Effect of Iranian Ministry of Health Protocols on Cesarean Section Rate: A Quasi-Experimental Study

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ABSTRACT

Background: High Cesarean section rate is a major health problem in developing countries. This study was established to evaluate the effectiveness of Iranian Ministry of Health and Medical Education protocols on Cesarean section rate trend.

Methods: Through a non-concurrent controlled quasi-experimental study, Cesarean section rate in Shohada-e-Tajrish and Taleghani hospitals in Tehran was compared during 2008-2009. Intervention group included 578 participants hospitalized because of premature rupture of membranes, prolonged pregnancy, pre-eclampsia, intra-uterine growth retardation, vaginal bleeding and premature labor in first and second trimester underwent interventions based on MOHME new protocol. On the other hand 594 cases as control group were selected during the same time before the intervention and underwent routine treatments. Descriptive statistics, t-test, chi square and univariate analysis were used when appropriate.

Results: Basic characteristics in two groups had no statistically significant difference. Cesarean section applied for 360 (67.8%) women in case group and on the other hand, 270 (48.8%) Cesarean sections were done for control group ($P<0.001$). There was 19 % difference between intervention and control groups. Complication of pregnancies had increased by 6% in intervention group ($P<0.001$). Mortality rate in the study was zero in both groups.

Conclusion: Applying clinical practice guidelines does not guarantee decreasing Cesarean section rate. Providing appropriate service may increase the ability of service providers to find more indications for Cesarean section.

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Introduction

The obstetricians and gynecologists have debated on the acceptable range for the Cesarean section rate in each country during recent years^{1, 2}. However, according to the WHO recommendations, a maximum of 15% of deliveries have medical indication for Cesarean section³. Nevertheless, the Cesarean section rate in Iran has risen significantly over the past few decades from less than 7% in the 1970s to more than 40% in 2005⁴, at the end of last decade Cesarean section constituted 47% of all deliveries in the country, 52% of total deliveries and 64% of deliveries in the private sector in Tehran (the Capital of Iran)^{5, 6}. This rate is much higher than many other developing⁷ and developed countries⁸.

Although women who give birth via Cesarean section may be at increased risk of negative health consequences^{9, 10} the demand for Cesarean section is so widespread, that it has actually altered the obstetrician landscape, making it a challenge to find a physician who will deliver a woman naturally through vaginal delivery¹¹. The government has broadcasted informing programs in media on the risk of Cesarean section for mothers and infants.

An issue of interest for reproductive health researchers is finding applied ways to reduce Cesarean section rate. One of the suggested solutions was to exert protocols to make hospitals more mothers friendly, which pro-

vide a better setting for naturally delivery¹². The most notable example of these attempts was national protocols published by the Ministry of Health and Medical Education (MOHME), Iran in 2008 for the first time. These protocols cover the most common pregnancy complications (including those mentioned in this study) and for each complication a protocol was developed by a team of experts in MOHME. Every complication was described through a user friendly algorithm of different situations. The emergency life threatening situations marked by red color, alarms of important but not life threatening situations defined by yellow and safe conditions by green color. Appropriate diagnostic and treatment approaches agreed upon included in algorithms and referring to other protocols has been proposed everywhere needed¹³.

Despite using these protocols unifies the practice of mother's health related professions, little has been previously done for developing evidence for effect of these protocols in reduction of Cesarean section rate trend¹⁴. In Iran these protocols are going to be generally recommended to be used in all hospitals and other obstetrics facilities, and MOHME need evidence for effectiveness of them. The aim of this study was to elaborate the effect of Iranian MOHME's new protocols on Cesarean section rate trend and defining the effect of different variables on pregnancy termination choices.

Methods

The non-concurrent controlled quasi-experimental study was performed in two general referral teaching hospitals- Taleghani and Shohada-e-Tajrish hospitals-affiliate to Shahid Beheshti University of Medical Sciences in Tehran, The capital of Iran. These hospitals were selected randomly through five gynecological teaching hospitals of Shahid Beheshti University of Medical Sciences. In Iran, each province at least, has a university of medical sciences which supervise some teaching hospitals. The referral pattern to the selected hospitals was the same as the other teaching hospitals of other provinces of Iran. Participants in our study were pregnant woman hospitalized in these hospitals from April 2008 to April 2009. Pregnant women hospitalized with non-pregnancy related reason, pregnant women expired before hospital arrival and those who refused participation in the study were excluded. Totally 1172 participants, 636 participants in Shohada-e-Tajrish hospital and 536 participants in Taleghani hospital were assessed.

Totally 578 participants fulfilled our inclusion criteria for intervention group during the period of December 2008 to April 2009. These pregnant women hospitalize because of premature rupture of membranes, prolonged pregnancy, pre-eclampsia, intra-uterine growth retardation, vaginal bleeding and premature labor in first and second trimester were entered to the study. They underwent interventions based on MOHME new protocols for managing these complications. These protocols were

written by an Iranian team of gynecologists in MOHME. On the other side, 594 pregnant women were selected as control group from time period of April 2008 to October 2008. These women hospitalized because of the same problems as intervention group but they were treated based on routine previous approaches and underwent no intervention based on the MOHME protocols. The number of samples in each diagnostic group for both groups of intervention and control was almost matched. The other conditions were the same for two groups in this period of time.

After providing detailed oral information to each participant and obtained written informed consent from all eligible participants, data gathering was done by trained resident of Obstetrics and Gynecology section for each hospitalized participant separately. Data gathering forms included questions about, demographic characteristics; cause of admission asked from pregnant women and then other variables such as primary and final diagnosis, duration of hospitalization, occurrence of complications happened after hospitalization which was extracted from their hospital records. The most important outcomes of this study were considered as change in Cesarean section rate and also complications after discharge.

After double data entry, the data of these two groups were compared together using SPSS version 16. Descriptive statics, *t*-test, chi square were used when appropriate. Logistic regression was used for estimating Odds Ratio (OR) and nationality, occupational status, education, insurance status and parity entered in the model as covariates. In this test Cesarean section was considered as dependent variable with two situation of "done" or "not done".

The study was approved by the Medical Research Ethics Committee of Shahid Beheshti University of Medical Sciences and was carried out in accordance with the Declaration of Helsinki.

Results

Mean age of intervention group was 27.8 (SD±5.80) and the mean age of control group was 27.6 (SD±5.83). These means had no statistically deference ($P=0.229$). Two groups were homogenous in basic characteristics as presented in Table 1. The educational level, insurance status, number of parity, nationality except for job situation in participants in intervention group and participants in control group had no statistically significant difference.

In general, numbers of visits by specialist, and duration of hospitalization in intervention group was significantly higher than control group as shown in Table 2.

Complication of pregnancies after discharge from hospital increased by 6% in intervention group as presented in Table 3.

Table 1: Odds ratio (OR) estimate of cesarean section according to the basic characteristic of participants based on receive interventional procedures

Variables	Intervention		Control		OR	P value
	N=578	%	N=594	%		
Nationality						
Iranian	535	92.56	539	90.74	1.00	-
Afghan	43	7.43	55	9.25	1.36	0.356
Occupation status						
Employed	51	8.82	39	6.56	1.00	-
Matron	527	91.17	555	93.43	2.18	0.011
Education						
Illiterate	88	15.22	85	14.30	1.00	-
Primary	98	16.95	89	14.98	0.69	0.183
Secondary	92	15.91	119	20.03	0.72	0.248
High school	191	33.04	211	35.52	0.62	0.076
Associate	78	13.49	71	1.95	0.90	0.735
Bachelor and higher	31	5.36	19	3.19	1.10	0.841
Insurance						
Insurant	464	80.27	459	77.27	1.00	-
Non insurant	114	19.72	135	22.72	1.21	0.313
Parity						
0	263	45.50	283	47.64	1.00	-
1	204	35.29	182	30.63	1.10	0.552
2	81	14.01	95	15.99	1.01	0.976
3	22	3.80	23	3.87	1.32	0.437
≥4	8	1.37	10	1.67	0.67	0.449

Table 2: Numbers of visits by specialist and duration of hospitalization based on intervention and Control groups

	Mean (SD)		P value
	Intervention	Control	
Number of specialist visits	10.4 (5.9)	9.2 (5.33)	0.001
Duration of hospitalization	3.5 (2.79)	3.1 (1.21)	0.001

Considering Cesarean section rate, when excluding those who their pregnancy was not terminated during the study (47 participants in intervention and 41 participants in control group), there was 19% difference in Cesarean section rate between intervention and control groups. Cesarean section applied for 360 women in case group and on the other hand, 270 Cesarean sections were done for

Table 3: Outcome of pregnancies divided by intervention and Control groups

Outcome of terminated pregnancy	Intervention		Control		P value
	N	%	N	%	
Outcome of terminated pregnancy					
NVD	90	16.9	193	34.9	0.001
Cesarean section	360	67.8	270	48.8	
Abortion	81	15.3	90	16.3	
Total	531	100.0	553	100.0	
Complications after discharge					
Yes	65	11.2	31	5.2	0.001
No	513	88.8	563	94.8	
Total	578	100.0	594	100.0	

Mortality rate in the study was zero in both groups. Odds Ratios for Cesarean section calculated for nationality, occupation, education, insurance, and parity calculated and has been presented with their related P values in Table 1. Among covariates, only occupational status has

considerable OR which was statistically significant (P=0.011).

Discussion

This study showed that implementing protocols do not guarantee decreasing the Cesarean rate. The Cesarean Section rate in intervention group of our study with 67.8% was significantly higher than control group and also previous studies^{15,16}. There are several descriptions for higher rate of Cesarean section in intervention group. First, this may be partly a reflection of global increase in the Cesarean rate¹⁷⁻¹⁹ and Iran is no of exception⁵. Second, the other description may be due to the ability of protocols in finding indications of Cesarean section which might be missed in previous approaches. Third, it is better described when considered that this study was hospital based and thus, another possible explanation for this higher rate was related to the referral nature of chosen centers which more complicated cases were hospitalized in these centers. Then, even higher rate of Cesarean section is acceptable. In order to control this source of selection bias both intervention and control group were hospital base. Even after matching the groups on this variable, the Cesarean section rate remained higher in intervention group compared to control group.

The other possible less probable explanations are as follows: (a) this may be accredited to the improved technology in detecting pre-birth distress based on news protocols²⁰, but it needs more comprehensive study with specific focus on this issue. (b) Tendency of pregnant women to Cesarean section may unconsciously affect physicians decision toward this diagnose²¹. (c) The low expenses of Cesarean section births compared to regular births as seen in other countries may increase tendency to this easy way of delivery²². (d) Reduction in pain tolerance threshold in women²³ following technology improvement and modernity especially in metropolitans and large cities

Among the covariates housewives were a predictor of choosing Cesarean section in this study. This situation increased the rate by two folds. Almost all the employed women were under coverage of health insurance. It seems that rules of insurance companies for checking the indications of Cesarean section for payment may limit their choices.

As regards the increasing rate of Cesarean is multifactorial and besides medical implications, other legal, cultural, and economical factors may affect it²⁴⁻²⁶. All these factors should be considered in order to decrease the Cesarean section rate. Changing providers' behavior is not possible only through presentation of scientific evidence alone and multi-level and multidisciplinary approach using behavior change theories is necessary⁶.

In this study, complication rate following Cesarean section increased almost six percent after discharge from the hospitals. Although in order to promote safe delivery

in mothers and improving the total outcomes of pregnancies, the MOHME has followed certain interventions in "mother friendly hospitals" such as child birth preparation classes and making rules and regulations for labor wards' standards. Our result showed creating behavior change in health care providers is more complex than they expected. Our study indicated that after applying protocols the number the complications of delivery were doubled which were not comparable with other studies^{27, 28}. This significant increase occurred in presence of grows in number of duration of hospitalization and numbers of specialist visits. One interpretation for increased complications could lie on interventional nature of the Cesarean section as a surgical procedure compared with vaginal delivery. In some cases, different approaches were suggested by MOHME and national educational guidelines. This diversity in approaches makes more complexity for specialists and as a result more unnecessary interventions.

After implementing these protocols, duration of hospitalization and number of specialist visits increased. Higher admission days could be another explanation for increased complications. All of these could increase the financial burden of obstetrics complications. In England each 1% rise in the Cesarean section rate would cost the five million pounds per year²⁷. Even though based on unclear financial circles in Iran like under-table payments, precise estimate for financial burden of Cesarean rate is unclear, it is clear that the health sector must spend huge amount of money in order to satisfy the fake need for Cesarean section due to new protocols.

One of the most important notes on these protocols is that they are based on non-national evidence. They are mainly extracted from text books of gynecology and obstetrics but we expect that protocols prepare from national evidence especially cost effectiveness studies. Based on the findings, MOHME should revise the protocols in terms of number of visits, duration of hospitalization, indications for Cesarean section to be more cost-effective with fewer complications based on relevant national evidences.

There were some limitations in this study. Despite the data were gathered using a rigorous methodology, but the non-concurrent controls was another limitation of this study. This method was chosen because of ethical issues. In these situations that we are going to test a hypothesis that there is some evidence on their effectiveness, it is better to use non-concurrent controls. Other variables such as payment method, medico-legal issues and patient preferences also may affect provider practice and views on performing Cesarean section, should be considered in future studies. Different factors such as increasing women level of education, employment and higher marriages age and decreasing intended number of deliveries, provider behavior and clinical factors, health insurance coverage, delivery at private hospital²⁹, can be mentioned as baseline cause of increasing rate of Cesarean section.

Therefore the impact of implementing such guidelines will depend on many factors, including using effective implementation strategies³⁰ unify polling system and attuned insurance mechanism with standardize national guidelines can be useful in this regard.

Conclusion

Applying clinical practice guidelines does not guarantee decreasing Cesarean section rate in hospital setting although it may decrease the total average in the community level. It depends on many different kinds of factors. Providing appropriate service may increase the ability of service providers to find more indications for Cesarean section which had been missed before.

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Conflict of interest statement

Author had no conflict of interest.

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