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Case Series

Indications, Patterns and Correlates of Immediate Adverse Maternal Outcome Following Instrumental Assisted Vaginal Delivery in Leku Primary Hospital, Sidama Zone, Ethiopia

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<u>ABSTRACT</u>

Background: Instrumental vaginal delivery involves either vacuum extractor or obstetric forceps to facilitate delivery of the fetus for maternal and fetal benefit. However, instrumental delivery could be associated with substantial maternal injuries and even death.

Objective: The aim of the study was to assess the patterns and correlates of immediate adverse outcome of assisted vaginal births in Leku primary hospital, Sidama Zone, Ethiopia.

Methods: This retrospective hospital based study was employed done among 406 instrumental births between January 2014 and January 2019. Study cases were traced using systematic sampling technique while data was extracted using pretested-structured questioner. Epi data version 3.1 was used for data entry and Statistical Package for Social Science (SPSS) version 22 was used for analysis.

Results: The overall rate of maternal adverse outcome was 17.6% and 24.9%. The rates of assisted vaginal births were 56.6% in vacuum extractors and 43.4% in forceps. The most frequent indications for instrumental deliveries were prolonged second stage of labour while the most common adverse maternal outcome was perineal tears. After adjustments for potential confounders in multivariate regression analysis, parity [AOR=8.654, 95% CI 3.382-22.147], prolonged second stage of labor [AOR=3.713, 95% CI 1.540-8.953], obstetric complication [AOR=3.418, CI 1.315-8.880], type of IVD [AOR=4.130, 95% CI 1.667-10.235] use of episiotomy [AOR=4.175, 95% CI 1.525-11.428], type of labor [AOR=4.214, 95% CI 1.860-9.548] and birth weight [AOR=1.345, 95% CI 1.558-3.240] were also determinants of maternal adverse outcome.

Conclusion: The overall rate of adverse maternal outcome was high. Episiotomy application, referred from other facility type of IVD, obstetric complication and type of labor were determinants of outcome variable. Thus, focusing on risk factors for adverse maternal outcome during instrumental vaginal delivery is mandatory in order to improve quality of care and improve maternal outcome.

Keywords: Instrumental delivery; Patterns; Maternal complication; Indication; Factors

ABBREVIATIONS

AOR-Adjusted Odds Ratio; CI-Confidence interval; OR-Odds Ratio; SPSS: Statically Package for Social Science.

INTRODUCTION

Approximately, 140 million births have undergone worldwide every year [1]. Above a third of maternal deaths have the result of complications during the time of birth [2,3]. Developing countries have accounted for 99% of global burden of maternal mortality [4]. Of which, sub-Saharan Africa has shared the largest proportion of maternal mortality about 66% [5]. Maternal mortality is unacceptably high in Ethiopia which accounts for 412 deaths per 100,000 live births in 2016 [6]. To prevent

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this burden especially in low and middle income-countries, an interventional strategy are crucial to improve quality of care during the time of birth [7,8]. An instrumental assisted vaginal delivery is one of the seven signal functions of the basic emergency obstetric care for either maternal or fetal benefits. Instrumental assisted vaginal delivery is vaginal delivery of a baby accomplished with forceps or vacuum [9]. The acceptable indications to perform assisted vaginal delivery were prolonged second stage of labour, non-reassuring fetal testing, elective shortening of second stage of labour and maternal exhaustion [10].

Instrumental deliveries should be available and accessible especially in poor-resource countries where caesarean delivery can be relatively unsafe or unfeasible [11]. The rates of instrumental deliveries have been reported to vary from country to country and even within the same country from one health care setting to other. The rate of instrumental deliveries varies over time and from country to country [12]. In South western Ethiopia, the rate of instrumental delivery was 10.3% [13].

The advantage of instrumental delivery is reducing birth asphyxia which is related with the duration of the second stage of labour [14]. Other advantages of instrumental delivery over caesarean section have lower health risks, faster health recovery and less health expenditure, shorter hospital stay and increasing subsequent spontaneous vaginal delivery [15-18]. The risks of cesarean delivery are also abnormal placentation, uterine scar rupture and subsequent caesarean section. Therefore, instrumental delivery can help in avoiding unnecessary caesarean section delivery and its risks.

However, instrumental assisted vaginal delivery is associated with maternal and neonatal morbidity and mortality [19]. According to Cochrane reviews, studies have shown that forceps delivery has a greater risk of maternal morbidities whereas vacuum extraction has a greater risk of fetal morbidities. The neonatal complications have been also reported to vary greatly from one health care setting level to other even within the same health care setting [20,21]. Fortunately, the complications due to instrumental delivery can be modified by early recognition and management of its contributing factors [22]. The operator must be familiar with the indications, application and skilled use of the particular instrument with universal guidelines can avert maternal and fetal complications [23].

Despite high maternal mortality and widely use of instrumental delivery, there is a scarcity of documented data on indication, pattern and determinants of maternal immediate adverse outcome during instrumental delivery in Ethiopia [24]. Hence, the purpose of this study was to assess indication, pattern and determinants of immediate adverse maternal outcome during instrumental assisted vaginal delivery at primary hospital in Sidama Zone, Ethiopia.

CASE STUDY

Study Design, Area, Period and Population

A hospital-based retrospective cross-sectional study was conducted at Leku primary hospital in Leku town, Sidama Zone. This town is located at 302 km far from capital city of the country (Addis Ababa). Currently, the town has only one health institution, namely Leku primary hospital has a predominantly rural catchment population around 60,000-100,000 for primary health care. This study was conducted over the past 3 years period from January 2014 to December 2019.

The source population for our study was all maternal records of instrumental assisted vaginal deliveries at Leku primary hospital from January 2014 to December 2019. The study population was sampled records of instrumental assisted vaginal deliveries at Leku primary hospital from January 2014 to December 2019. The complete records of instrumental assisted vaginal deliveries were included in the study. However, the lost or incomplete records of instrumental deliveries were excluded from the study.

Sample Size and Sampling Techniques

A single population proportion formula was used to determine the sample size by considering the following assumptions: 59.8% magnitude of IVD complications, 95% confidence interval, 5% margin of error and 10% for incomplete data. The final sample size of this study was 406.

All records of instrumental assisted vaginal delivery during the study period (from January 2014 to December 2019) were sketched from maternal registration log book. Sampling frame was prepared by listing instrumental assisted vaginal delivery cases during study period. Then, simple random sampling technique was used to select the study subjects from sampling frame by using random number table.

Variable Measurement

Instrumental assisted vaginal delivery: Refers the use of instrument either vacuum extractor or forceps to shorten the process of vaginal birth

Immediate adverse maternal outcome: Refers to mothers who had at least one complication following instrumental assisted vaginal delivery like perineal tears, episiotomy extension, postpartum hemorrhage, vaginal and cervical tear, uterine rapture, maternal death.

Prolonged second stage of labour: Defined as the duration of delivery after full dilatation of the cervix is delayed in primiparous >2 hours without epidural anesthesia or >3 hours with epidural anesthesia and in multiparous >1 hours without epidural anesthesia for or >2 hours with epidural anesthesia.

Shortening of second stage of labour: Refers to the fastening fetal birth after full dilatation of the cervix due to maternal co-morbidity like obstetric hemorrhage, hypertension disorders, cardiac disorders and anemia which excludes maternal pushing efforts.

Poor maternal effort: Refers to inability of mothers to deliver the newborns due to physical exhaustion.

Episiotomy: Refers to surgical incision of the perineum with scissors to make more space of vaginal opening during second stage labor.

Indications of IVD: Refers to precondition for the application of instrumental assisted delivery either vacuum or forceps applications.

Study Variables

Dependent variable: The outcome of this study was maternal complication. The presence of at least one or more any form

of immediate maternal complication after instrumental vaginal delivery was dichotomized as Yes (coded as 1). The absence of any form of immediate maternal complication after instrumental vaginal delivery was dichotomized as No (coded as 0).

Independent variables: Independent variables include age, marital status, residence, parity, gestational age, birth weight, type of IVD, care provider, use of episiotomy, duration of second stage labor, type of labor, birth weight and obstetric complication (gestational diabetes, cardiac disease, anemia, obstetric hemorrhage, hypertensive disorders).

Instrumentation and Data Collection Procedures

The data was collected from delivery and postnatal registrations using a semi-structured and pretested questioner. The tool was developed by the investigators after reviewing of different literatures and it was prepared in English. The tool was developed by the investigators after reviewing of different literatures and it was prepared in English. The data included demographic characteristics (age, marital status and residence), obstetric and delivery characteristics (gestational age, parity, birth weight, care provider, use of episiotomy, type of IVD, amniotic fluid, referred from other facility and duration of second stage labor), obstetrical complication (cord prolapse, obstetric hemorrhage, hypertension disorders, anemia, diabetic mellitus, cardiac disease), information of instrument (type of IVD, indications) and maternal complication (Perineal tears, PPH, episiotomy extension, cervical and vaginal tear, urine retention and paraurethal tears). Delivery registration book was used to obtain card number of cases with instrumental delivery. Then, maternal birth records/charts was used to extract the required data. Three BSC midwives were recruited for data collection in this study.

Data Quality Assurance

The consistence of the questionnaire tool was checked by the experts of obstetrics and midwifery before actual data collection. The pretest was employed on 5% of study sample of maternal delivery records to test the applicability of the tool. Maternal delivery records of pretest were excluded from the study sample. One-day training was given to data collectors about the study objectives, sampling procedures, inclusion and exclusion criteria. The data collection process was checked and coordinated by supervisors and the principal investigator to ensure the completeness and consistency of the collected data.

Data Processing and Analysis

The extracted data were entered to Epi-data version 3.1 then the data were exported and analyzed by Statistical Package for Social Science (SPSS) version 22. The distribution of each study variables (frequencies, percentages, means and standard deviations) were described by descriptive analyses. The association between study independent variables and immediate maternal adverse outcome were investigated by bivariable and multivariable logistic regression analysis. Study independent variables having p-value ≤ 0.25 during bivariate logistic regression anal yses were declared for advance multivariate logistic regression analysis to control confounders. Finally, independent variables having p-value <0.05 using adjusted OR with 95% CI were declared as predictors of immediate adverse maternal outcome.

Ethical Consideration

The ethical approval for the study was obtained from Institutional Review Board of Hawassa University College of medicine and health sciences. The data was collected and its confidentiality was secured throughout the study after the permission of Leku primary hospital administration office.

RESULTS

Socio-Demographic Characteristics

Four hundred six respondents were enrolled in the current study. One hundred seventy (49.9%) mothers were between 25 years-35 years with a mean of 27.43 ± 4.02 years. Two hundred eighty seven (84.2%) of study cases were married and two hundred eighty seven (82.7%) were rural residents (Table 1).

 Table 1: Maternal sociodemographic characteristics at Leku Primary

 hospital from January 2014 to December 2019.

| Variables | Frequency | Percentage | | | |
|--------------------|-----------|------------|--|--|--|
| Age range | | | | | |
| <25 | 64 | 18.8 | | | |
| 25-35 | 170 | 49.9 | | | |
| >35 | 107 | 31.4 | | | |
| Marital status | | | | | |
| Single | 21 | 6.2 | | | |
| Married | 287 | 84.2 | | | |
| Divorced | 17 | 5 | | | |
| Widowed | 16 | 4.7 | | | |
| Place of residence | | | | | |
| Urban | 59 | 17.3 | | | |
| Rural | 282 | 82.7 | | | |

Obstetric and Reproductive Related Factors

One hundred three (53.7%) of cases were not referred from other health facility whereas 46.3% of them were referred as emergencies. Two hundred thirty six (69.2%) participants had normal labour while the rest (30.8%) had prolonged labor. One hundred fifty eight (46.3%) of study cases were nulliparous while only (53.7%) were multiparous. Three hundred twenty four (95.0%) instrumental deliveries were performed by Master holders (MSc) in Integrated Emergency Surgery and Obstetrics (IESOs) and the rest of them were done by midwives. Three hundred sixteen (92.7%) of mothers had <4000 grams of birth weight babies whereas only 44 (7.3%) had >4000 grams of birth weight babies. Two hundred twenty four (65.7%) cases had no episiotomy procedure during instrumental delivery whereas only 117 (34.3%) cases had episiotomy. Two hundred thirty five (68.9%) mothers had spontaneous labor while one hundred six (31.1%) were induced/augmented with oxytocin. Most of 288 (84.5%) participants had no obstetric complication whereas only 53 (15.5%) had obstetric complication. One hundred ninety four (56.9%) mothers were assisted with vacuum delivery and only one hundred forty seven (43.1%) cases were assisted with forceps delivery (Table 2).

 Table 2: Obstetric and reproductive characteristics of the study participants after instrumental assisted vaginal delivery at Leku Primary hospital from January 2014 to December 2019.

| Variables | Frequency | Percentage | | | | |
|------------------------------|----------------------|------------|--|--|--|--|
| Parity | | | | | | |
| Nulliparous | 158 | 46.3 | | | | |
| Multiparous | 183 | 53.7 | | | | |
| Referred from other facility | | | | | | |
| No | 183 | 53.7 | | | | |
| Yes | 158 | 46.3 | | | | |
| Durat | ion of second stage | e labor | | | | |
| Normal | 236 | 69.2 | | | | |
| Prolonged | 105 | 30.8 | | | | |
| | Birth weight | | | | | |
| <4000 | 316 | 92.7 | | | | |
| ≥ 4000 | 44 | 7.3 | | | | |
| Ot | stetric complicatio | n | | | | |
| No | 288 | 84.5 | | | | |
| Yes | 53 | 15.5 | | | | |
| Ту | pe of birth attendar | it | | | | |
| MSc holders in IESOs | 324 | 95 | | | | |
| Midwives | 17 | 5 | | | | |
| | Type of IVD used | | | | | |
| Vacuum | 194 | 56.9 | | | | |
| Forceps | 147 | 43.1 | | | | |
| Use of episiotomy | | | | | | |
| No | 224 | 65.7 | | | | |
| Yes | 117 | 34.3 | | | | |
| Type of labor | | | | | | |
| Spontaneous | 235 | 68.9 | | | | |
| Induced/augmented | 106 | 31.1 | | | | |

Indication and Patterns of Maternal Complication

Concerning indication, the most frequent clinical indications of instrumental assisted vaginal delivery were fetal distress 178 (52.2%), poor maternal effort 119 (34.9%), Shortening Second Stage of Labor (SSOL) due to comorbidity 28 (8.2%) and prolonged second stage of labour 16 (4.7%). Regarding maternal complication, the overall rate of maternal complication was 58 (17%). The more frequent immediate maternal complications following instrumental delivery were 23 (29.7%) perineal tears (1st ,2nd and 3rd degree), 16 (14.0%) Primary Postpartum Hemorrhage (PPH), 7 (12.0%) extension of episiotomy, 4 (6.9%) cervical and vaginal tear, 5 (8.6%) urine retention and 3 (5.1%) paraurethal tears. Perineal tears, Primary Postpartum Hemorrhage (PPH) and cervical and vaginal tear are more frequent maternal complications in forceps assisted deliveries while episiotomy extension was more frequent maternal complication in the vacuum deliveries.

Determinants of Immediate Maternal Complication

Bivariate analysis: Parity, prolonged second stage of labor, birth weight, obstetric complication, type of IVD, use of episiotomy and type of labor were identified as candidate variables during bivariable logistic regression analysis for further multi variable logistic regression for adjustments of potential confounders.

Multivariate analysis: Obstetric complication, type of IVD, use of episiotomy, type of labor, parity, birth weight and duration of labor were significantly associated with increasing immediate maternal adverse outcome. Mothers with obstetric complication were 3.4 times [AOR=3.418, 95% CI 1.315-8.880] more likely to develop immediate maternal complication during instrumental delivery compared with counterparts. The likelihood of developing maternal complication among mothers who had forceps-assisted vaginal delivery were 4.1 times [AOR=4.130, 95% CI 1.667-10.235] more than those had vacuum extraction. Mothers had episiotomy during instrumental delivery were 4.1 times [AOR= 4.175, 95% CI 1.525-11.428] more likely to have immediate maternal complication compared with counterparts. The likelihood of developing maternal complication following instrumental delivery among primiparous were 8.7 times [AOR=8.654, 95% CI 3.382-22.147] more than multiparous. Mothers had prolonged second stage of labor during instrumental delivery were 3.7 times [AOR=3.713, 95% CI 1.540-8.953] more than normal second stage of labor. The likelihood of developing maternal complication following instrumental delivery among mothers had induction/augmentation were 4.2 times [AOR=4.214, 95% CI 1.860-9.548] more than spontaneous labor. Mothers had newborns with birth weight \geq 4000 grams were 4.2 times [AOR=1.345, 95% CI 1.558-3.240] more likely to have maternal complication compared with those had newborns with birth weight <4000 grams (Tables 3 and 4).

Table 3: The rate of maternal complications/morbidities following instrumental deliveries among study subjects between January 2014 and December 2019 in Leku primary hospital, Ethiopia.

| Immediate maternal compli- cations | Vacuum (%) | Forceps (%) | Total (%) |
|---|------------|-------------|-----------|
| Perineal tears (1 st , 2 nd and 3 rd degree) | 7 (12.1) | 16 (27.6) | 23 (29.7) |
| Post-Partum Hemorrhage (PPH) | 4 (6.9) | 6 (7.1) | 16 (14.0) |
| Episiotomy extension | 5 (8.6) | 2 (3.4) | 7 (12.0) |
| Cervical and vaginal tear | 1 (1.7) | 3 (5.2) | 4 (6.9) |
| Urine retention | 2 (3.4) | 3 (5.2) | 5 (8.6) |
| Paraurethal tears | 1 (1.7) | 2 (3.4) | 3 (5.1) |

 Table 3: Multivariate analysis of associated factors for adverse and in the maternal outcome among study subjects between January 2014 and the December 2019 in Leku primary hospital, Ethiopia.

| Variables | Having maternal compli- cation | | Crude OR (95% CI) | Adjusted OR (95% CI) |
|-------------|-----------------------------------|-----------|--|-------------------------|
| | No (%) | Yes (%) | | |
| | | Parity | | |
| Multiparous | 164 (89.6) | 19 (10.4) | 1 | 1 |
| Nulliparous | 119 (75.3) | 39 (24.7) | 2.829 (1.557- 8.654 (3.382- 5.139) 22.147)* | |

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| Duration of second stage labor | | | | | | |
|-------------------------------------|------------------|-------------|--------------------------|---------------------------|--|--|
| Normal | 219 (92.8) | 17 (7.2) | 1 | 1 | | |
| Prolonged | 64 (61.0) | 41 (39.0) | 8.253 (4.394- 15.499) | 3.713 (1.540- 8.953)* | | |
| | | Birth weigh | t | | | |
| <4000 | 271 (85.8) | 45 (14.2) | 1 | 1 | | |
| ≥ 4000 | 18 (72.0) | 7 (28.0) | 6.238 (3.213- 12.109) | 1.345 (1.558- 3.240)* | | |
| Obstetric complication ^a | | | | | | |
| No | 244 (84.7) | 44 (15.3) | 1 | . 1 | | |
| Yes | 39 (73.6) | 14 (26.4) | 1.991 (.999- 3.968) | 3.418 (1.315- 8.880)* | | |
| | Type of IVD used | | | | | |
| Vacuum | 167 (86.1) | 27 (13.9) | 1 | 1 | | |
| Forceps | 116 (78.9) | 31 (21.1) | 1.653 (.937- 2.916) | 4.130 (1.667- 10.235)* | | |
| Use of episiotomy | | | | | | |
| No | 208 (92.9) | 16 (7.1) | 1 | 1 | | |
| Yes | 75 (64.1) | 42 (35.9) | 7.280 (3.864- 13.716) | 4.175 (1.525- 11.428)* | | |
| Type of labor | | | | | | |
| Spontaneous | 208 (88.5) | 27 (11.5) | 1 | 1 | | |

Induced/augmented 75 (70.8) 31 (29.2) 3.184 (1.784- 4.214 (1.860-5.685) 9.548)*

Note: ^aObstetric complication include hypertension disorders, obstetric hemorrhage, cardiac disorders and anemia *Statistically significant association p-value < 0.05, 1 Referent category.

COR: Crude Odds Ratio, AOR: Adjusted Odds Ratio, IVD: Instrumental Vaginal Delivery

DISCUSSION

Vacuum-assisted vaginal delivery (56.9%) was the most frequent instrumental assisted vaginal deliveries in our study. This result was supported by other studies [25]. The reason of vacuum delivery preference may be due to need less expertise for correct application and lower morbidities for mothers [26]. The other reason for the preference of vacuum extractor may be due to operator convenience and lack of skills on the use of forceps.

The most frequent clinical indications for instrumental assisted deliveries were fetal distress. The same finding was reported in other studies [27]. However, prolonged second stage of labor and poor maternal efforts were the most common clinical indication for instrumental assisted vaginal deliveries in other studies [28-32]. These variations may be due to different study settings and designs, the lack of knowledge and skills on the application of instrumental delivery.

In our study, the overall rate of immediate adverse maternal outcome following instrumental assisted vaginal delivery was 17.6%. This value was greater than other different studies [33]. These differences could be due to the nature of methods, lack of skills/expertize knowledge and availability of instruments. The frequency of maternal injury was higher compared with the forceps delivery. This finding was supported with other evidences. The most frequent maternal adverse outcome was

perineal tears followed by postpartum hemorrhage. This finding was supported with other different reported evidences. The possible explanation of perineal tears following instrumental delivery may be due to unable to give an episiotomy or extension of episiotomy. The possible reason of postpartum hemorrhage may also secondary to delay in repairing or suturing the genital tears and episiotomy. The rate of cervical and vaginal wall tears was 6.9%. This value was greater than other study. The rate of episiotomy extension was 12.0%. This value was less than other study [34]. But it was greater than other study. The rate of paraurethal tears and urine retention were 5.1% and 8.6% respectively. This value was greater than other study. The reason of disparities in rates may be due to lack of well-trained/expertize on the use of instrument and different study methods.

Mothers delivered newborns without episiotomy during instrumental assist vaginal delivery were 5.3 times [AOR=3.4, 95% CI 1.08-10.67] more risk of immediate adverse maternal outcome compared with those delivered with episiotomy. This was supported with other study. Other evidences have shown that the use of episiotomy in assisted vaginal delivery protects the risk of maternal anal sphincter injuries [35]. Neonatal birth weight \geq 4000 grams were 2.8 times more likely (AOR=2.8, 95%) CI: 1.8-4.2) to have immediate maternal adverse outcome compared with neonatal birth weight <4000 grams. This result was consistent with other studies. This findings was also proven in other studies that macrosomia attributes for PPH secondary to uterine atony and perineal injuries [36]. Mothers delivered newborns with instrumental delivery followed by prolonged labour were 3.7 times more risk for immediate maternal adverse outcome. The other evidences supported our findings that prolonged labor is associated with maternal morbidity like dehydration, exhaustion or rupture of the uterus, perineal trauma, and maternal infection and hemorrhage [37-39]. Forceps-assisted vaginal delivery was 3.4 times [AOR=3.4, 95% CI 1.08-10.67] more likely to have immediate adverse maternal outcome compared to vacuum-assisted vaginal delivery. This supported with other study. This finding was supported based on cochrane review that forceps delivery has a higher risk of maternal injuries and deaths. Primiparous mother with instrumental vaginal delivery was 5.3 times [AOR=3.4, 95% CI 1.08-10.67] more likely to have immediate adverse maternal outcome compared with multiparous mother. A possible reason of maternal complication may be secondary to a higher tendency of delayed second stage in nulliparous women leading to a high risk for perineal injuries [40].

CONCLUSION

The rate of maternal adverse outcome following assisted vaginal birth was high in our study. The most common indication for assisted instrumental vaginal delivery was fetal distress. Perineal tear was the most frequent adverse maternal outcome. The determinant variables of adverse maternal outcome were obstetric complication, IVD type, episiotomy, labor type, parity, birth weight and labor duration. Thus, focusing on risk factors of adverse maternal outcome in instrumental vaginal delivery is recommended in order to improve quality of care and prevent maternal life threatening injuries and mortalities.

LIMITATION OF THE STUDY

Firstly, the limitation of our study was unavailability of some risk factors due to a retrospective study. Secondly, the cause and effect relationship between dependent and independent variables cannot be measured because of cross-sectional design. Thirdly, this study was done in a primary hospital since it might not be a representative for other health care level settings like health centers, general and referral hospitals. Fourthly, long-term neonatal complication of instrumental assisted vaginal delivery could not be assessed due to the lack of recorded information.

COMPETENT INTEREST

The authors declare no personal, organizational or financial conflicts of interest.

AUTHORS' CONTRIBUTION

GK and TM proposed the study, contributed to the design, analyzed the data, interpreted the results and wrote the manuscript. AA and MG wrote the first draft, collected the data; reviewed manuscript. The final manuscript was read and approved by four authors.

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AVAILABILITY OF DATA AND MATERI-

ALS

All relevant data are within the paper.

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