

Original article

Non-Steroidal Anti-Inflammatory Drugs Consumption and Awareness About Risks During Pregnancy In AL-Bayda City, Libya

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Abstract

Non-steroidal anti-inflammatory drugs are one of the most common prescribed medications for relieving pain, fever, and inflammation. Most NSAIDs are available without a prescription, and they often consumed by pregnant women for short periods of time to treat mild pain. However, these drugs can cause substantial teratogenic effects. NSAIDs such as aspirin, diclofenac sodium and ibuprofen might cause oligohydramnios (low amniotic fluid) or prenatal renal abnormalities if taken in the late second half of pregnancy. The US Food and Drug Administration (FDA) announced that taking NSAIDs in the period from the fifth month of pregnancy to delivery is not safe. This research was conducted to explore pregnant women's knowledge about NSAIDs during gestation period as well as consumption patterns. This study was conducted during the period from 10/2/2022 to 10/3/2022 in private clinics in Al-Bayda, Al-Quba cities as well as Al -Thawra hospital targeting 250 pregnant women who asked gently to fill in a printed questionnaire. The questionnaire has a variety of questions regarding age, consumption of NSAIDs during pregnancy and awareness about the benefits and risks of these drugs. Our study indicated that 55.6% of the pregnant women were in the range of twenty-two to twenty-nine years old. Half of pregnant women (50%) did consume painkillers (NSAIDs). Aspirin was the most common drug (55%). Forty-five out of 125 were consuming these drugs without prescription (36%). The common reason for consuming NSAIDs was varicose veins (31%). 30.4% of pregnant women had a miscarriage. Poor fetal growth was the most common cause of miscarriage among 29% of participants. Sixty-five percent of the participants knew that using this kind of drugs in the last month of pregnancy affect their health negatively. Only 4% of them had miscarriage due to consumption of NSAIDs. Pain management noticed in 90% of pregnant women. Awareness about the positive and negative effects of NSAIDs was noticed in 55% of the participants. In conclusion, despite the fact which is consumption of NSAIDs throughout pregnancy has undesirable effects on pregnant women and fetus, these drugs are widely prescribed by doctors to pregnant women. NSAIDs should not be prescribed during pregnancy unless mother's outcomes exceed the possible fetal adverse effects. Our research found no significant relation between NSAIDs consumption in the period of pregnancy and miscarriage. Although our results were satisfied, concentrated education programs are needed to spread knowledge in our society and another research must be conducted on a large sample size to investigate the differences among this study with the current research.

Keywords: Pregnancy, Consumption of NSAIDS, Awareness, Miscarriage.

Introduction

Non-steroidal anti-inflammatory drugs are antipyretic, analgesic, and anti-inflammatory medication which relieve fever, pain and inflammation [1]. Although most diseases concern inflammation, this sort of medication like aspirin, diclofenac sodium, naproxen and ibuprofen are frequently prescribed to pregnant women to relieve pain, fever as well as inflammation. Inflammatory bowel and chronic rheumatic diseases are the most common illnesses experienced by most pregnant women [2].

For more than 50 years, NSAIDs, especially ibuprofen, have been recommended in premature delivery because of its efficacy to relax the smooth muscles of uterus and delay labor for 2 days up to 10 days maximum [3]. It has been found that self-medication with these drugs is common in the period of pregnancy [4]. This kind of drugs can cross the placenta and cause fetal and neonatal complications (oligohydramnios and premature ductus arteriosus) regarding the name of the drug used, the dose, the duration of treatment as well as the period of NSAIDs administration [5]. All these neonatal complications result from the inhibition of prostaglandins production which caused by NSAIDs and from the physiological changes in the maternal's absorption, distribution, metabolism as well as elimination of these drugs in the period of pregnancy. The common consumed NSAIDs are Ibuprofen, diclofenac, aspirin, indomethacin, such these drugs have been linked with abortion [6].

All these kinds of medications have analgesic, anti-inflammatory and antipyretic actions apart from acetaminophen which has no anti-inflammatory effect. NSAIDs inhibit the production of hormone-like substances called prostaglandins by inhibiting COX1 and/or COX2 enzymes, therefore NSAIDs are categorized according to their selectivity for COX1 and COX2. Aspirin, ibuprofen, and diclofenac inhibit both COX 1 and COX2 while drugs like celecoxib can inhibit COX2 only. The gastrointestinal adverse effects are not common with the last drug because it inhibits COX2 only [7].

Prostaglandins have a crucial role in induction of pain, fever, and inflammation by rising temperature and dilating blood vessels resulting in swelling and redness at the site of release [8, 9].

There are various side effects of NSAIDs, minor such as: ulcer, diarrhea, nausea, vomiting, and constipation. Major problems such as: dizziness, problems with balance, difficulty in concentrating, mild headache, kidney, and platelet dysfunction [10]. The most dangerous side effect of NSAIDs during pregnancy is miscarriage, especially during the first few months of pregnancy [11]. Various studies have discovered that the risk of abortion is extensively increased with the consumption of NSAIDs in early pregnancy. In spite of the fact that data have not always been persistent, there is ancient evidence for the relation between NSAIDs consumption and miscarriage; NSAIDs inhibit prostaglandins production which are crucial for fetus implantation. So, the risk of abortion builds up in the case of atypical implantation [12]. Consumption of NSAIDs after 30 weeks of pregnancy can result in the appearance of fetal deformity like oligohydramnios and premature closure of fetal ductus arteriosus [13]. Various abnormalities in lung, kidney, brain, heart, skeleton, and digestive tract have been recorded after fetal susceptibility to NSAIDs [14]. There is not enough information to confirm that exposure to NSAIDs is unsafe [15,16]. However, these drugs should not be prescribed during pregnancy unless mother's outcomes exceed the possible fetal adverse effects, at the minimum therapeutic dose and not for extended period.

This survey aimed to evaluate the common prescribed NSAIDs, potential causes of miscarriage, awareness as well as knowledge about consumption of NSAIDs during pregnancy in Al-Bayda and Al-Quba cities.

Methods

Study design

A cross-sectional survey involving self-administered questionnaire was conducted on 250 pregnant women enrolled at private clinics in two cities (Al -Bayda and Al-Quba) as well as Al-Thawra hospital, Al-Bayda, Libya during February and March 2022.

Data collection

The total number of questionnaires is 250 copies which distributed randomly to pregnant women. A semi-structured questionnaire was implemented to pick up the information. The questionnaire consists of two sections: the first was sociodemographic characteristics (include: name, age) and the second part was questions about pattern of NSAIDs consumption (include: type of consumed drugs, frequency, rate of abortion, awareness, and knowledge about side effects).

Statistical analysis

Microsoft EXCEL program (2010) was used to tabulate data and to calculate frequencies and percentages.

Results

Two hundred and fifty questionnaires were distributed and included finally, ending with a 100% response rate. 55.6% of pregnant women were in the range of 22 - 29 years old, only one was in the range of 46-49 as shown in table1.

Table1. Age distribution.

Age	NO	%
18-21	26	10.4%
22-25	70	28%
26-29	69	27.6%
30-33	34	13.6%
34-37	25	10%
38-41	19	7.6%
42-45	6	2.4%
46-49	1	0.4%

According to the findings of our research, half of the contributors (50%) claimed that they never take any type of painkillers during their pregnancy, while the rest did consume these kinds of medications (Fig 1).

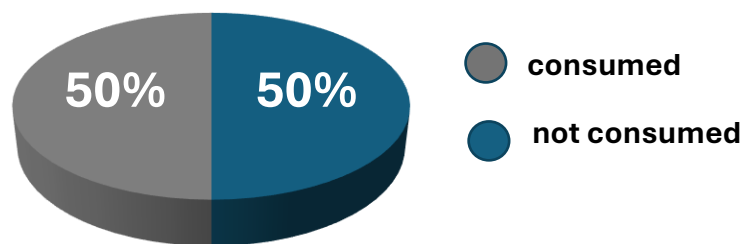


Figure 1. Distribution of NSAIDs consumers regarding if they consume painkiller or not.

It is interesting that most participants (64%) did consume the painkillers by a medical prescription, and they have been informed to stop taking this kind of drugs in the third trimester, while 36% of them consumed this kind of drugs by their own as illustrated in figure 2.

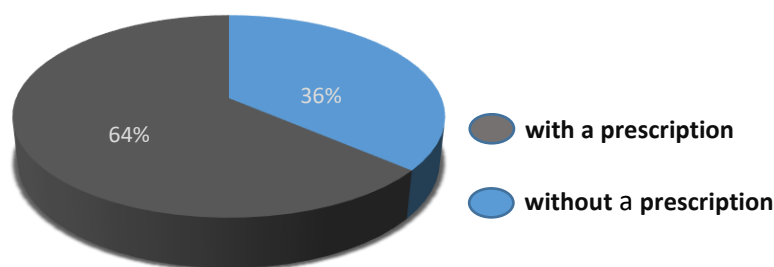


Figure 2. Distribution of NSAIDs consumers regarding consumption of painkillers with or without a prescription.

In our survey, we found that 30% of pregnant women reported that they had a previous miscarriage, while 70% of them did not miscarry before as shown in figure 3.

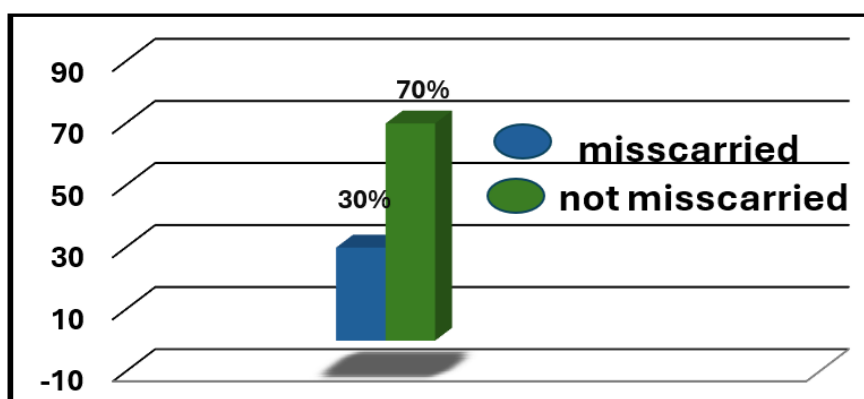


Figure 3. Distribution of NSAIDs consumers regarding the rate of abortion.

The present study found that only 4% of participants had miscarriages due to consumption of NSAIDs during their pregnancy. The most common cause of miscarriage was poor fetal growth (29.3%), while car accidents (1.3%) and COVID (1.3%) were the weakest causes of miscarriage as shown in figure 4.

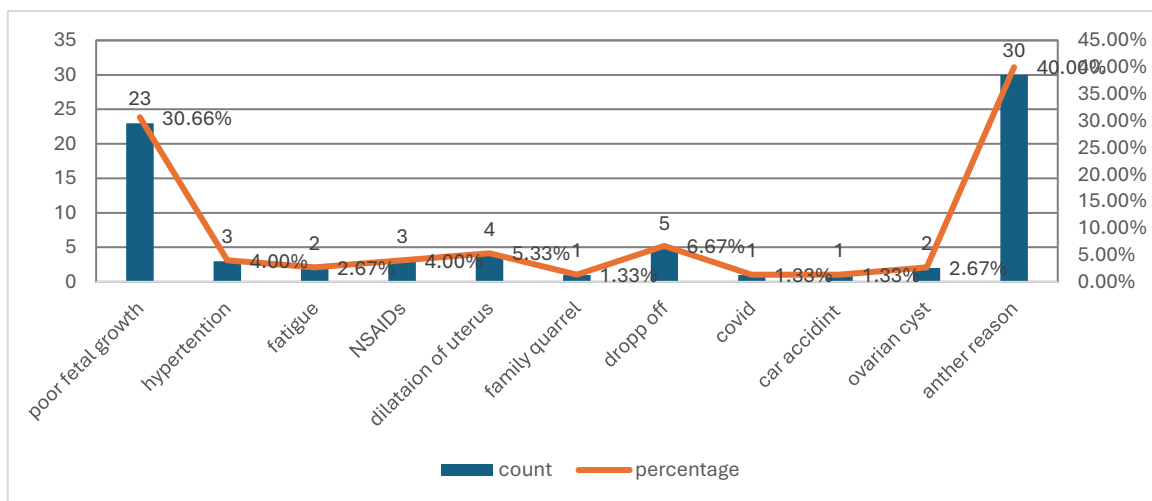


Figure 4. Distribution of NSAIDs consumers regarding causes of miscarriage.

In addition, 81% of pregnant women reported that they consumed NSAIDs once a day, 17% of them consumed these dugs twice a day while only 2% consumed the painkillers three times a day as shown in figure 5.

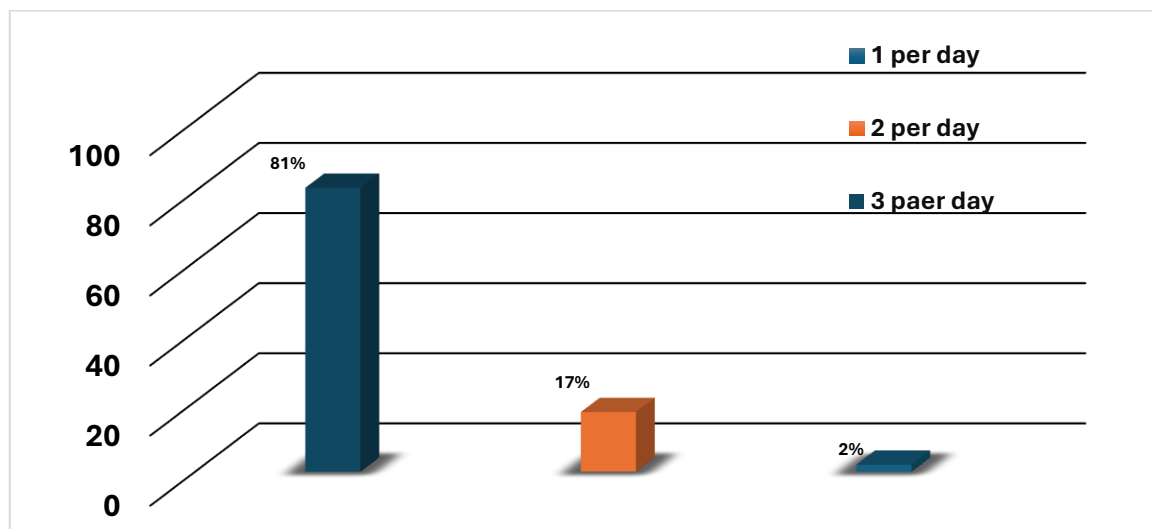


Figure 5. Distribution of NSAIDs consumers regarding times of painkillers used.

Our study found that Aspirin (55%) was the most common used drug by participants Compared to other drugs in the same Category as illustrated in figure 6. The reason for this result is because of aspirin is a blood thinning agent and is commonly prescribed to prevent blood Clots in women who had varicose veins.

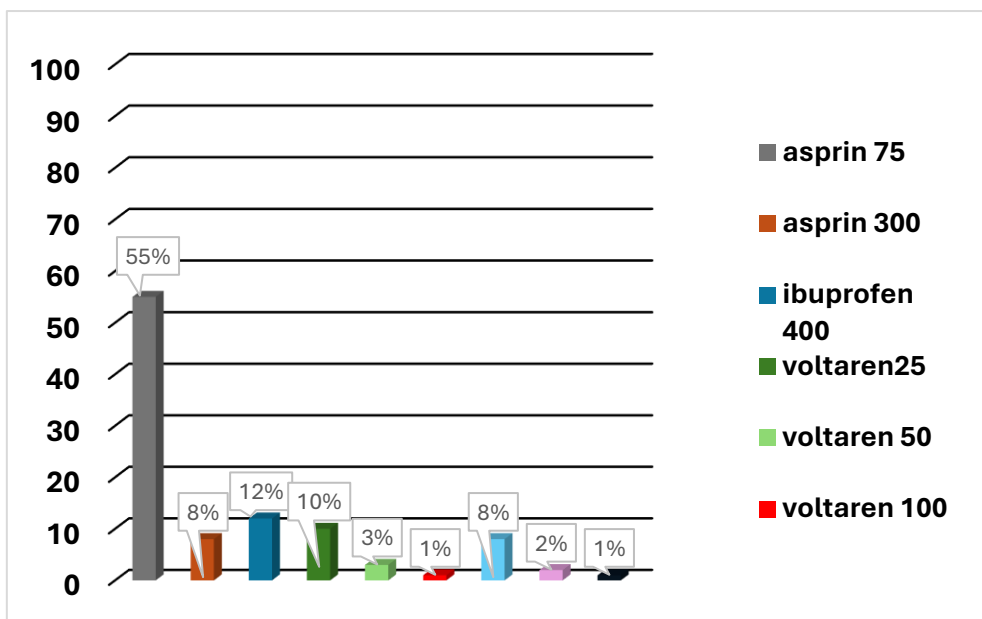


Figure 6. Distribution of NSAIDs consumers regarding types of painkillers used.

The most common diseases which force the pregnant women to consume NSAIDs were varicose veins (31%) followed by toothache (16.9%) and then back pain (16.1%) and vaginal infection (13%) as shown in figure 7.

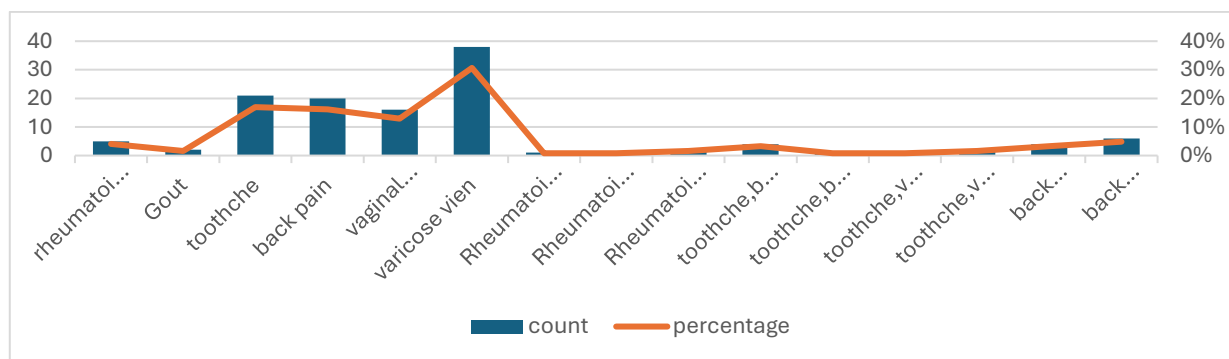


Figure 7. Distribution of NSAIDs consumers regarding reasons for taking painkillers.

The finding of this survey showed that most pregnant women (90%) improved after consuming the Painkillers, while only 10% did not improve after the consumption of these drugs as illustrated in figure 8.

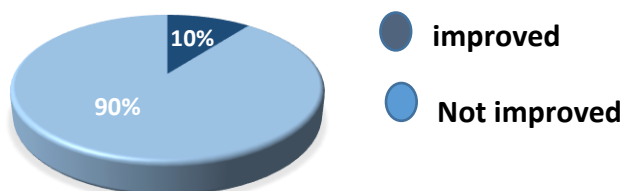


Figure8. Distribution of NSAIDs consumers according to if they improved or not after treatment.

In addition, it is good that only 18% of pregnant women did feel mild adverse effects after taking NSAIDS Such as peptic ulcer, diarrhea or constipation and nausea, while most of them (82%) did not feel any side effects after consuming NSAIDS (Fig 9).

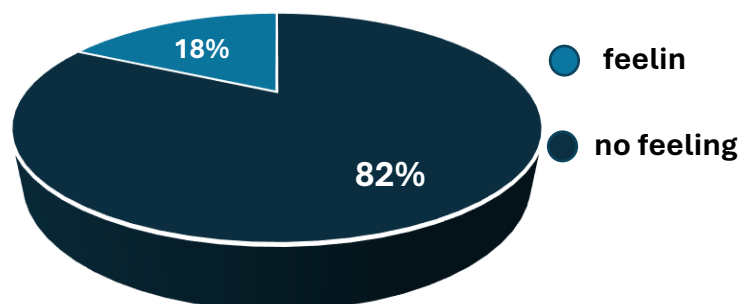


Figure 9. Distribution of NSAIDs consumers regarding feeling of side effects after consumption.

Forty-five percent of participants claimed that they were not aware of the adverse effects of NSAIDs on their body in the first months of pregnancy, while more than half claimed that they knew the adverse effects of consuming NSAIDs on their bodies and fetuses (Fig 10).

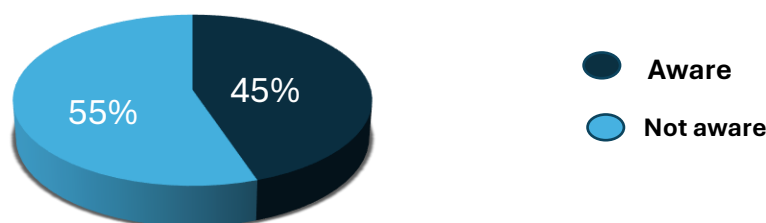


Figure 10. Distribution of NSAIDs consumers regarding awareness about side effects of painkillers in the early pregnancy.

It was satisfying that 65% of pregnant women knew the fact that NSAIDs may cause harmful effects on their fetuses (Fetal ductus arteriosus and oligohydramnios) if they consumed these drugs in the last months of Pregnancy as shown in Figure 11.

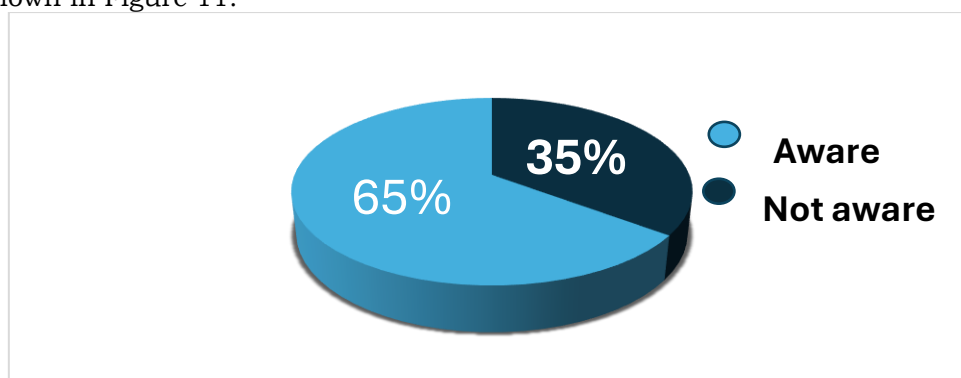


Figure 11. Distribution of NSAIDs consumers regarding awareness about the negative effects of painkillers in the last three months of pregnancy.

Discussion

Non-steroidal anti-inflammatory drugs are considered as analgesic, anti-inflammatory and pain relievers [17]. Aspirin as well as ibuprofen and diclofenac are the most prescribed medications in this category. NSAIDs inhibit cyclooxygenase enzyme which plays a crucial role in the production of hormone like compounds called prostaglandins that are responsible for pain, elevated temperature, and inflammation. NSAIDs cause a variety of adverse effects including irritation, heartburn, diarrhea, constipation, ulcers, nausea, and vomiting [18]. NSAIDs are routinely consumed by pregnant women to cure pain, fever as well as inflammation.

This recent study investigated the consumption patterns of NSAIDs between pregnant women in two cities: Al-Bayda, Al-quba, Libya applying a survey questionnaire. The objective was to explore the knowledge level of pregnant women about consumption of NSAIDs during pregnancy. The obtained data demonstrates that prevalence of NSAIDs consumption with a prescription between pregnant women (64%) was dramatically high. The reason for this finding is understandable as 65% of the participants knew that consuming NSAIDs during late pregnancy affect their health negatively.

Varicose veins were the most common reason for taking painkillers with a rate of 31%. In congruence with this finding, the results of the study, conducted by Judy Slome Cohain, showed that about 30% of women progress varicose veins throughout pregnancy because of raised blood volume by about 1200 ml through gestation period [19]. This outcome is inconsistent with a study conducted by *Rose Ann Z Masa et al*, which they found that headache and backache were the most popular reasons for consuming NSAIDs [20].

In our survey, aspirin 75mg (known as cardio protective agent) is widely prescribed to pregnant women to facilitate early placentation, thus facilitate the passage of nourishments as well as oxygen to the fetus [21,22]. This survey found that the most common prescribed NSAIDs is aspirin with a rate of 55%. In comparison with studies conducted by *Ongbinde AT et al* and *Alpaslan Gokcimen et al*, which found that diclofenac sodium was the most prescribed NSAIDs [23, 24].

Using NSAIDs for prolonged periods of time throughout early pregnancy is associated with a raised risk of miscarriage as well as fetal abnormalities. According to this study results, regarding miscarriage, poor fetal growth was the most common cause of abortion in 29% of pregnant women, while COVID infection was the weakest cause of miscarriage among pregnant women (n=1). This finding was in accordance with a survey conducted by *Janneke A.C. van Baarlet et al* [25].

The results offered that there was no incidence of increased spontaneous abortion because of specific NSAIDs, we found that only 4% of pregnant women miscarried because of NSAIDs consumption in the first and second trimester. This finding agrees with a study conducted by *Sharon Daniel et al* [26]. On other hand, our finding was disagreeing with research conducted by *Durudogan L*, which confirmed that using NSAIDs in the first months of pregnancy resulted in exaggerated increase in the risk of miscarriage [27]. Furthermore, a survey conducted in 2018 by *Anne Marie Z et al* which showed that the consumption of NSAIDs around the time of conception raised the miscarriage risk 4-fold higher in the period of early pregnancy [28]. Furthermore, the small sample size (n= 250) which evolved in our survey might be the cause of disagreement with a study conducted by *Dekun Li et al* and *Ying, XH et al*, which they claimed that the percentage of women who miscarried because of painkillers was very high [29, 30].

The retardation of prostaglandins synthesis which is caused by NSAIDs through a reversible inhibition of cyclooxygenase enzyme is thought to be the cause of renal impairment. NSAIDs limit renal perfusion by blocking prostaglandin production and decreasing prostaglandin receptor activation. This may cause a decrease in the generation of prenatal urine, which is the predominant supply of amniotic fluid especially in the period at 12 weeks - 24week of gestation [12]. Moreover, our study did not report even one case with oligohydramnios after maternal consumption of NSAIDs. In comparison with a study conducted in 1980 by *Cantor et al*, which recorded the first occurrence of oligohydramnios, and most cases had no negative neonatal effects after the discontinuation of drug consumption. However, in certain situations, this complication(oligohydramnios) reappeared within 3 to 6 days even after stopping NSAIDs consumption or when the same NSAIDs was consumed. Premature infants of women who consumed NSAIDs in the period of pregnancy are more susceptible to acute renal insufficiency (7.38-fold) higher than controls, according to this research. Type, dose and duration of NSAID used varied between these reports [31].

Recently, in 2020, US FDA Drug Safety Communication has announced that NSAIDs are categorized as one of the most teratogenic drugs [32]. According to the study results, 55% of women were aware about side effects of NSAIDs, while 45% of them were not educated about adverse effect of NSAIDs consumption in early pregnancy. These outcomes agreed with a study conducted by *Michel Baltouni* [33]. Ninety percent of them felt better after taking NSAIDs, while 10% of them did not feel well, and 82% of them did not feel any side effects after taking NSAIDs, while only 18% suffered from mild side effects.

In this research, we noticed that most participants have been informed to stop using this kind of medication in the third trimester. In comparison with a study conducted by *V Cejvanovic et al*, they confirmed that thousand pregnant women were still exposed to NSAIDs in this time of pregnancy [34]. Specifically, we found that 65% of the participants knew that using NSAIDs in the last months of pregnancy affect fetal health negatively (Ductus arteriosus constriction, oligohydramnios). This outcome reflects the elevated level of education among pregnant women which is inconsistent with the result of a study done by *Chaelgn Kassaw et al*, which reported that, the education level among pregnant women is poor [35].

According to the survey results, the incomes illustrated that only a small proportion of pregnant women who were exposed to consumption of ibuprofen and diclofenac (12% and 10%) respectively have been informed to discontinue the consumption in the second and third trimesters. These outcomes agreed with a study conducted by *Katarina Dathe et al*, which found that consumption of diclofenac and ibuprofen for long time in the second and third trimesters can result in ductus arteriosus constriction in five out of 1092 cases [36]. In addition, another study was conducted by *K Nezvalova-Henriksen et al*, which illustrated the effects of

ibuprofen as well as voltaren on the pregnancy outcomes, the results approved that consumption of ibuprofen in the second and third trimesters can result in low birth weight and asthmatic symptoms in 18 months old respectively, while exposure to diclofenac in the second and third trimesters can lead to underweight newborn and maternal vaginal bleeding with no neonatal complications have been recorded [37].

Conclusion

In summary, the study confirmed that, there is a satisfied level of education between pregnant women about NSAIDs consumption, and we believed that it could represent pregnant women in general in Libya. Varicose veins were the most common illness experienced by 31% of pregnant women who exposed to NSAIDs. Even though using NSAIDs during pregnancy has negative effects on pregnant women, just 4% of those who participated in this survey had miscarriage because of using NSAIDs. However, we suggest that pregnant women must be aware about misusing and risks of NSAIDs consumption and more standardized research are needed to investigate the pattern and widespread of NSAIDs consumption among pregnant women in various cities in Libya and multimedia programs may be helpful in educating the entire community about the risks of NSAIDs consumption during pregnancy.

Conflicts of interest

The authors declare no conflicts of interest.

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المستخلص

تعتبر مضادات الالتهاب غير الستيرويدية من أكثر الأدوية الموصوفة شيوغًا لتخفيف الألم والحمى والالتهاب. معظم مضادات الالتهاب غير الستيرويدية متاحة بدون وصفة طبية، وغالبًا ما تستهلكها النساء الحوامل لفترات قصيرة من الوقت لعلاج الألم الخفيف. ومع ذلك، يمكن لهذه الأدوية أن تسبب تأثيرات جانبية كبيرة. مضادات الالتهاب غير الستيرويدية مثل الأسبرين وديكلوفيناك الصوديوم والإيبوبروفين قد تسبب قلة السائل الأمنيوسي (انخفاض السائل الأمنيوسي) أو تشوهات الكلى قبل الولادة إذا تم تناولها في أواخر النصف الثاني من الحمل. أعلنت إدارة الغذاء والدواء الأمريكية أنه لا ينصح بتناول مضادات الالتهاب غير الستيرويدية في الفترة من الشهر الخامس من الحمل وحتى الولادة. تم إجراء هذا البحث لاستكشاف معرفة النساء الحوامل حول مضادات الالتهاب غير الستيرويدية أثناء فترة الحمل بالإضافة إلى أنماط الاستهلاك. أجريت هذه الدراسة خلال الفترة من 2/10/2022 إلى 10/3/2022 في العيادات الخاصة في مدينة البيضاء والقبة وكذلك مستشفى الثورة واستهدفت 250 امرأة حامل حيث طلبنا منهن ملء استبيان مطبوع. يحتوي الاستبيان على مجموعة متنوعة من الأسئلة المتعلقة بالعمر واستهلاك مضادات الالتهاب غير الستيرويدية أثناء الحمل والوعي بفوائد ومخاطر هذه الأدوية. أشارت دراستنا إلى أن 55.6% من النساء الحوامل تتراوح أعمارهن بين 22_29 سنة. نصف النساء الحوامل (50%) يتناولن مسكنات الألم (مضادات الالتهاب غير الستيرويدية). وكان الأسبرين هو الدواء الأكثر شيوغًا (55%). وكان 45 من أصل 125 يتناولون هذه الأدوية دون وصفة طبية (36%). وكان السبب الشائع لتناول مضادات الالتهاب غير الستيرويدية هو الدوالي (31%). 30.4% من النساء الحوامل تعرضن للإجهاد. كان ضعف نمو الجنين هو السبب الأكثر شيوغًا للإجهاد بين 29% من المشاركات. 65% من المشاركات كن يعرفن أن استخدام هذا النوع من الأدوية في الشهر الأخير من الحمل يؤثر على صحتهن سلبًا. فقط 4% منهن تعرضن للإجهاد بسبب تناول مضادات الالتهاب غير الستيرويدية. لوحظت إدارة الألم لدى 90% من النساء الحوامل. ولوحظ الوعي بالآثار الإيجابية والسلبية لمضادات الالتهاب غير الستيرويدية لدى 55% من المشاركات في الختام، على الرغم من أن تناول مضادات الالتهاب غير الستيرويدية طوال فترة الحمل له آثار غير مرغوب فيها على النساء الحوامل والجنين، إلا أن هذه الأدوية توصف على نطاق واسع للنساء الحوامل. لا ينبغي وصف مضادات الالتهاب غير الستيرويدية أثناء الحمل إلا إذا تجاوزت نتائج الأم التأثيرات الضارة المحتملة على الجنين. لم يجد بحثنا أي علاقة ذات دلالة إحصائية بين استهلاك مضادات الالتهاب غير الستيرويدية في فترة الحمل والإجهاد. وعلى الرغم من أن نتائجنا كانت مرضية، إلا أن هناك حاجة إلى برامج تعليمية مركزة لنشر المعرفة في مجتمعنا ويجب إجراء بحث آخر على عينة كبيرة الحجم لمعرفة الاختلافات بين هذه الدراسة مع البحث الحالي.