Introduction

According to the World Health Organization (WHO), patient safety is defined as “the prevention of errors and adverse effects to patients associated with health care” and “to do no harm to patients”. Because medical errors and complications define, to a large degree, what patient safety is, understanding their roles in patient safety is essential to improve the delivery of health care. A medical error can be defined as a failure to achieve the desired medical outcome, which may result in an unfavorable but preventable outcome. A medical complication is a morbid process due to a medical intervention for which the outcomes may or may not be expected and independent of the physician’s will. The two concepts, though used interchangeably by the public, have a different meaning.

Abstract

Background: Basic understanding of medical errors and medical complications is essential to ensure patient safety. Our aim in this study was to assess whether patients have sufficient knowledge of medical errors and medical complications and to identify the factors that influence their knowledge. Methods: A cross-sectional study was conducted with 400 patients with a scheduled appointment at King Abdulaziz Medical City from 2019 to 2020. A self-administered validated questionnaire was developed by the coinvestigators. The first section focused on demographic information, and the second contained 17 scenarios to assess the knowledge of the patients. The data were analyzed with Chi-square test and logistic regression. Results: The sample size realized as 346 (n = 346), with the majority (n = 198, 57%) female, and the mean age 39.5 ± 11 years. The mean scores for the medical errors and complications were 5.5 ± 2.10 and 4.8 ± 2.3, respectively. The participants with secondary education were less likely to have sufficient knowledge of both medical complications (OR 0.52, P = 0.016) and errors (OR 0.52, P = 0.016). In terms of age, the older participants, the 38–47 year age group, were less likely to be knowledgeable about medical complications compared to the younger age groups (OR 0.92, P = 0.046). Conclusion: The patients had a higher level of knowledge about medical errors compared to medical complications. The level of education and the employment status significantly predicted the knowledge of both medical errors and complications.

Keywords: Medical complications, medical errors, knowledge, patient education, patient safety

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Despite the increased emphasis on patient safety, errors and adverse outcomes are still prevalent in clinical practice. In 2013, a study conducted in Saudi Arabia indicated the prevalence of medical errors as 35.8%.[6,7] In the Middle East, minor studies have been conducted, but they only explored limited aspects of the topic. Similarly, on a global level, the prevalence of medical errors is yet to be documented.[8] Medical errors and complications are a burden for patients and their families, in terms of mortality and finance, as adverse events due to unsafe practice is the 14th leading cause of death and injury globally.[9] The annual Irish hospital losses are estimated to be 194 million € (Euros) due to adverse events alone, as reported by The Irish National Adverse Events Study.[10]

Medical errors are confused by many factors, varying from the influence of the media’s stories of malefance to the lack of communication between health care providers and patients, in the presence of inevitable adverse events.[11-14] The lack of awareness of medical errors and complications results in an increase in lawsuits filed against medical professionals. However, 60% of all filed lawsuits due to medical malpractice are dismissed for having no justifiable reasons supporting the claims.[15,16]

In spite of the documented high rate of medical errors and complications, most studies focused on the incidents or an assessment of the physician attitudes to both. The views of health care users are crucial for improving medical practice, as a positive patient experience is associated with compliance, increased knowledge, and positive outcomes.[17,18]

This study aimed to assess patients’ knowledge regarding medical errors and medical complications and to identify the associated factors influencing the level of knowledge, in contrast to prior studies investigating only one of the topics. The focus was on treatment-related errors, as classified by the Institute of Medicine, as the associated adverse events are more detectable than any other type.[19]

Methods

The study used a cross-sectional design, and the data were collected with a structured questionnaire. This study design was chosen to measure the outcome and the exposure at the same time with no future follow-up. The study was conducted at King Abdulaziz Cardiac Centre (KACC), and the Department of Medicine, King Abdulaziz Medical City, Riyadh, Saudi Arabia. Both KACC and the Internal Medicine Division of the Department of Medicine provide a variety of medical services, supporting the inclusion of a variety of patients with different conditions and varying levels of knowledge. The period of recruitment was from September 2019 to May 2020. The calculated sample size was 385, which was rounded up to 400. Calculations were done using Raosoft with a 5% margin of error, 95% level of confidence, and assumed 50% prevalence, because there was no previous study to serve as the reference value.[20] The inclusion criteria were literate male and female patients, 18–65 years old, from all nationalities, and present in the waiting area. The eligible participants were included using a convenient sampling technique. The participants who complied with less than four criteria were excluded, resulting in 346 completed questionnaires (response rate: 86.5%).

A two-part questionnaire was designed by the co-investigators, after a thorough literature review. The questionnaire consisted of 17 close-ended items that were vignettes of frequently experienced incidents related to medical complications and errors, with three possible response options (yes, no, I don’t know). The outcome variables were the patients’ level of knowledge about medical errors and medical complications. The patient’s gender, age, education level, employment, having a chronic disease and health care background, duration on medications, personal medical error experience, familiarity with the terms medical error and medical complication, and the source of their medical information were considered as the independent variables of the study. The questionnaire was designed in English and then translated to Arabic. All the steps of the translation process and adaptation of instruments were done for the finalization of the questionnaire.[21,22] For validation purposes, content validation was done by three experts, and their feedback was considered.

A pilot test was done with 30 participants. The questionnaire involved 15 vignettes, which were presented in two versions to compare how it would affect the reliability. Half, 15 copies, provided definitions of medical errors and medical complications, the other half did not. As a rule of thumb, the sample size for pilot testing is based on the number of items, and for each item, three participants were included. Internal consistency was determined by measuring the reliability coefficient, Cronbach alpha, which showed good reliability for both versions. Based on the comments from the first pilot testing, five questions were added, the definitions of medical errors and complications were removed, a category of “do not know” was added as some participants reported to have no knowledge of the scenarios. The improved questionnaire was distributed to 60 participants for a second pilot test. After analyzing the results, the reliability coefficient Cronbach alpha of all items was 0.71. The medical error items had a reliability of 0.75 and the medical complication items, 0.62. Some items were rephrased, some of the newly added items with lower reliability were excluded, and the definitions were kept as their deletion lowered the reliability in the second trial. They were provided as a reference for the participants when completing the questionnaire.

The study received ethical approval from the Institutional Review Board (No: SP19/077/R). An informed consent form accompanied every questionnaire, and no medical or personal data were collected. The co-investigators distributed the questionnaire and collected the data which was only accessible to them.

The data were entered in Microsoft Excel and checked for correctness. The file was transferred to the Statistical Package for Social Scientists (SPSS) for analysis.
for Social Sciences (SPSS) version 22 for analysis. To clean the data, initial descriptive statistics were done. The medical error and complication-related items were recorded, based on the correct responses. Each correct response was scored as 1, and the final scores for the medical complications and errors were computed by the summation of the correct responses. The score range for the medical complications was 0–9 and for the medical errors 0–8. The cut-off score for having sufficient knowledge of medical complications was set at 5.94, and 5.28 for medical errors. The cut-off was calculated based on a double of what can be achieved by random testing (scores >66%). The categorical variables are presented as a proportion of the sample of 346. The numerical variables such as age and total scores for medical complications and medical errors are reported as mean and standard deviation. Age was stratified in age groups of 18–27, 28–37, 38–47, and ≥48 years. To assess the association of the demographic variables and the level of knowledge as a categorical variable, a Chi-square test was used. For assessing the predictors of sufficient knowledge about medical complications and medical errors, the binary logistic regression was applied and the odds ratio with 95% confidence intervals. The P value was set at 0.05 for all the tests.

**Results**

In total, 346 questionnaires were completed. The majority (n = 198, 57%) was female, with the highest proportion in the 28–37 year age group (n = 101, 29.2%) (mean age: 39.5 ± 11 years). More than half (n = 192, 56%), achieved higher education and 190 (55%) were unemployed. The majority (n = 316, 91%) did not have a health care background, and 191 (55%) did not have any chronic illness. Most patients were using medication (n = 216, 62%). The majority (n = 233, 67%) did not rely on social media as a source of medical information and 270 (78%) had no experience of medical errors. In terms of familiarity with the terms, more patients indicated that they were familiar with the term “medical errors” (n = 252, 73%), than the term “medical complications” (n = 204, 59%) [Table 1].

The mean score for the medical errors and complications were 5.58 ± 2.1 and 4.9 ± 2.3, respectively. The proportion with sufficient knowledge (scores >66%) was higher for medical errors (n = 219, 63%), compared to medical complications (n = 145, 42%).

In terms of medical complications, Item 12 related to constipation as a side effect of iron had the highest proportion of correct responses (n = 231, 67%). The item with the smallest proportion was item 15, which assessed bleeding as a side effect of aspirin (n = 85, 25%). Regarding medical error–related knowledge, the item with the highest proportion of correct responses was Item 10, involving a prescription of blood pressure medication without proper investigation (n = 294, 85%), and the lowest was Item 13, an example of a near-miss medical error (n = 152, 44%) [Tables 2 and 3].

The majority (n = 68, 71%) of the group with sufficient knowledge about medical errors, was in the “48 years and above” age group, which was statistically significant (P = 0.04, \( \chi^2 = 7.9 \)). Similarly, of the 198 females, 63 (32%) had sufficient knowledge regarding medical errors, which was significantly higher than the male group (P = 0.03, \( \chi^2 = 7.9 \)). The employment status and health care background variables were significantly associated with knowledge of medical complications. Of the group with a background in health care, 12 (40%) had sufficient knowledge of medical complications which was statistically

| Variables                                  | Categories | n (%)  |
|--------------------------------------------|------------|--------|
| Age Categories (years)                     | 18-27      | 59 (17) |
|                                            | 28-37      | 101 (29) |
|                                            | 38-47      | 90 (26)  |
|                                            | 48 and above| 96 (28) |
| Gender                                    | Female     | 198 (57) |
|                                            | Male       | 148 (43) |
| Education level                           | Intermediate or less| 45 (13) |
|                                            | Secondary  | 109 (32) |
|                                            | Higher education | 192 (56) |
| Employment status                         | Employed   | 156 (45) |
|                                            | Unemployed | 190 (55) |
| Health care background                     | Yes        | 30 (9)   |
| Any chronic illness                       | Yes        | 155 (45) |
| Are you using any medication?             | Yes        | 216 (62) |
| Do you rely on medical information from social media? | Yes | 113 (33) |
| Experienced medical error?                | Yes        | 76 (22)  |
| Familiarity with the term “medical error” | Know the term | 252 (73) |
|                                           | Heard of it | 87 (25)  |
|                                           | Never heard of it | 7 (2)   |
| Familiarity with the term “medical complication” | Know the term | 204 (59) |
|                                           | Heard of it | 102 (30) |
|                                           | Never heard of it | 40 (12) |

| Medical Complication Items                  | Incorrect n (%) | Correct n (%) |
|--------------------------------------------|-----------------|---------------|
| Item 1                                     | 141 (41)        | 205 (59)      |
| Item 3                                     | 190 (55)        | 156 (45)      |
| Item 4                                     | 121 (35)        | 225 (65)      |
| Item 7                                     | 123 (36)        | 223 (65)      |
| Item 8                                     | 158 (46)        | 188 (54)      |
| Item 12                                    | 115 (33)        | 231 (67)      |
| Item 14                                    | 189 (55)        | 157 (45)      |
| Item 15                                    | 261 (75)        | 85 (25)       |
| Item 16                                    | 122 (35)        | 224 (65)      |

| Medical Error Items                        | Incorrect n (%) | Correct n (%) |
|--------------------------------------------|-----------------|---------------|
| Item 2                                     | 151 (44)        | 195 (56)      |
| Item 5                                     | 112 (32)        | 234 (68)      |
| Item 6                                     | 139 (40)        | 207 (60)      |
| Item 9                                     | 60 (17)         | 286 (83)      |
| Item 10                                    | 52 (15)         | 294 (85)      |
| Item 11                                    | 60 (17)         | 286 (83)      |
| Item 13                                    | 194 (56)        | 152 (44)      |
| Item 17                                    | 69 (20)         | 277 (80)      |

For details about each item’s content, check Table 3
Two variables, the level of education and the employment status were identified as significant predictors of both medical error and complication knowledge. The participants with a secondary education were less likely to be knowledgeable about medical errors (OR 0.52, CI: 0.30 to 0.88, \( \chi^2 = 24 \)) and complications (\( \chi^2 = 12 \)). The proportions in the higher education group with sufficient knowledge about medical errors and complications were 50% and 73%, respectively [Table 4] [Figure 1].

Regarding employment status, 75 (48%) of the employed participants had sufficient knowledge of medical complications, which also significant (\( P < 0.001, \chi^2 = 12 \)). The level of education was significantly associated with being knowledgeable about medical errors (\( P < 0.001, \chi^2 = 24 \)) and complications (\( P < 0.003, \chi^2 = 12 \)). The proportions in the higher education group with sufficient knowledge about medical errors and complications were 50% and 73%, respectively [Table 4] [Figure 1].

Medical Complication Items

- Item 1: "Eye drops were prescribed for a patient then she felt burning sensation"
- Item 3: "A patient complained of blurred vision after surgery that required anesthesia"
- Item 4: "A patient complained of bruises over the area were the blood was drawn"
- Item 7: "A patient started to vomit in the recovery room after general anesthesia"
- Item 8: "doctor prescribed a drug for hypertension as needed and the patient developed cough during the period of therapy"
- Item 12: "A doctor prescribed iron supplement, then the patient complained of constipation after taking the supplements"
- Item 14: "A patient developed infection after surgery"
- Item 15: "A doctor prescribed an aspirin for a patient who has blood clots and he developed internal bleeding"
- Item 16: "A doctor prescribed a medication to manage a patient’s acne, but the acne progressed as a normal body reaction"

Medical Error Items

- Item 2: "A patient is taking iron supplements, but his condition didn’t improve because the doctor didn’t warn him to avoid drinking coffee with the supplements"
- Item 5: "A patient received a physical therapy after a hand surgery, but the therapist exaggerated the area, which caused the patient to repeat the surgery"
- Item 6: "A patient was given a drug orally although he has difficulty in swallowing"
- Item 9: "A doctor prescribed a contraindicated drug to a diabetic patient, then the patient developed renal failure after intake"
- Item 10: "a drug was prescribed for hypertensive patient without measuring the patient’s blood pressure"
- Item 11: "A patient received blood transfusion. Later on, they found that blood donor had HIV"
- Item 13: "A nurse missed a medication dose that was supposed to be given to a patient, but there was no harm"
- Item 17: "A doctor prescribed warfarin (a blood thinner) to a patient without asking if the patient is taking other blood thinners"
HS which also noted that females had better knowledge of medical errors. Those who had higher education acquired significant scores, unlike their other counterparts. This finding is similar to two other studies in which higher education had better scores. All of these studies regarding medical errors, however, showed associations between younger ages and higher knowledge, whereas our results revealed that older participants were the ones who obtained high knowledge levels. There could be two explanations; either due to some studies have maintained a focus on medication errors exclusively, or due to older individuals’ tendency to presume the occurrence of medical errors over medical complications when their contexts are presented simultaneously. Although medical errors could be considerably more understood by the general population, item 13 which represented a near-miss medical error did score low among other medical error scenarios, as it was rather perceived as a medical complication. This could be explained by the fact that half of physicians would not disclose an error unless it affects patient outcomes.

Concerning the knowledge level of medical complications, higher levels were similar to medical errors’ in that they were associated with higher education. But on the contrary to medical errors, medical complication knowledge was further significantly associated with being employed and having a background in health care. Additionally, first-hand experience of medical errors has marginally shaped how correspondents answered medical complication scenarios accurately. All these findings could reflect the enhancement of one’s exposure to medical complications and the ability to share experienced knowledge with other

Table 4: Association of demographic characteristics with the level of knowledge

| Variables                              | Categories               | Insufficient Knowledge n (%) | Sufficient Knowledge n (%) | $P$  |
|----------------------------------------|--------------------------|------------------------------|---------------------------|------|
| Age Categories (years)                 | 18-27                    | 31 (53%)                     | 28 (48%)                  | $\chi^2=2.4$, $P=0.49$ |
|                                        | 28-37                    | 55 (55%)                     | 46 (46%)                  | $\chi^2=0.09$, $P=0.75$ |
|                                        | 38-47                    | 55 (61%)                     | 35 (39%)                  | $\chi^2=0.36$, $P=0.56$ |
|                                        | 48 and above             | 60 (63%)                     | 36 (38%)                  | $\chi^2=0.03$, $P=0.03$ |
| Gender                                 | Female                   | 113 (57%)                    | 85 (43%)                  | $\chi^2=0.19$, $P=0.56$ |
|                                        | Male                     | 88 (60%)                     | 60 (41%)                  | $\chi^2=0.32$, $P=0.132$ |
| Education level                        | Intermediate or less     | 29 (64%)                     | 16 (36%)                  | $\chi^2=12$, $P<0.001^*$ |
|                                        | Secondary                | 76 (70%)                     | 33 (30%)                  | $\chi^2=0.19$, $P=0.65$ |
|                                        | Higher education         | 96 (50%)                     | 96 (50%)                  | $\chi^2=0.00$, $P=0.03$ |
| Employment status                      | Employed                 | 75 (48%)                     | 81 (52%)                  | $\chi^2=0.00$, $P=0.03$ |
|                                        | Unemployed               | 126 (66%)                    | 64 (34%)                  | $\chi^2=0.00$, $P=0.03$ |
| Healthcare background                  | Yes                      | 12 (40%)                     | 18 (60%)                  | $\chi^2=4.4$, $P<0.001^*$ |
|                                        | No                       | 90 (58%)                     | 65 (42%)                  | $\chi^2=0.00$, $P=0.99$ |
| Chronic illness                        | Yes                      | 124 (57%)                    | 92 (43%)                  | $\chi^2=0.1$, $P=0.74$ |
|                                        | No                       | 67 (59%)                     | 46 (41%)                  | $\chi^2=0.09$, $P=0.751$ |
| Using any medication                   | Yes                      | 122 (65%)                    | 64 (35%)                  | $\chi^2=0.00$, $P=0.03$ |
|                                        | No                       | 96 (49%)                     | 41 (51%)                  | $\chi^2=3.5$, $P=0.05$ |
| Relying on social media for health information | Yes | 37 (49%)                     | 39 (51%)                  | $\chi^2=3.5$, $P=0.05$ |
|                                        | No                       | 32 (32%)                     | 28 (48%)                  | $\chi^2=2.4$, $P=0.49$ |

Table 5: Predictors of medical complication and medical error knowledge

| Independent Variables                  | Knowledge of Medical Complications | Knowledge of Medical Errors |
|----------------------------------------|-----------------------------------|----------------------------|
|                                        | Odds Ratio [95% CI]               | $P$                        | Odds Ratio [95% CI] | $P$ |
| Age† (years)                           |                                    |                            |                         |     |
| 28-37                                  | 0.58 [0.28-1.17]                   | 0.13                       | 1.43 [0.69-2.98]       | 0.333 |
| 38-47                                  | 0.47 [0.22-0.99]                   | **0.046**                  | 0.92 [0.44-1.93]       | 0.836 |
| 48 and above                           | 0.56 [0.26-1.19]                   | 0.132                      | 1.65 [0.76-3.57]       | 0.202 |
| Female gender‡                         | 1.47 [0.89-2.43]                   | 0.133                      | 1.33 [0.80-2.21]       | 0.277 |
| Education level                        | Intermediate or less              | 0.74 [0.36-1.55]           | 0.431                   | 0.46  [0.22-0.99] |
|                                        | Secondary education               | 0.52 [0.30-0.88]           | **0.016**               | 0.28  [0.16-0.49] |
|                                        | Unemployed                         | 0.61 [0.23-0.72]           | **0.002**               | 1.93  [1.08-3.46] |
|                                        | No health care background          | 0.81 [0.35-1.86]           | 0.614                   | 0.56  [0.22-1.41] |
|                                        | Chronic illness                    | 0.79 [0.47-1.33]           | 0.375                   | 1.00  [0.59-1.71] |
|                                        | No firsthand medical error experience | 0.61 [0.35-1.04]       | 0.071                   | 0.78  [0.43-1.40] |

Significant Chi-square values ($P<0.05$). Significant logistic regression ($P<0.05$). Reference category is “yes”, “male” for gender, “higher education” for education level, and “employed” for employment status. Reference category is “no”, CI: Confidence Interval.
individuals. This is in concordance with El-Nagar et al.’s study which observed that only one-quarter of participants had a fair knowledge of obstetric complications because few were employed and had higher education.\(^{[30]}\) In another contradicting observation documented by a study of Slankamenac et al., patients had similar perceptions to those of physicians and nurses in terms of the severity ranking of postoperative complications, however, one can argue that the study focused on the severity of complications rather than general complication contexts.\(^{[32]}\) From the current study, the medical complication example expressed in item 15 obtained the lowest rate of correct answers. Item 15 assessed the knowledge of aspirin side effects, and the majority of the participants decided bleeding was not a complication of aspirin. The finding is similar to a study conducted by Siddig et al. in Saudi Arabia.\(^{[33]}\)

One of the most crucial outcomes in this study is that binary logistic regression revealed associations between acquiring sufficient knowledge on both medical errors and medical complications and education level and employment status. This yet again reinforces the substantial impact employment and higher education have on patients’ health knowledge. It is also of benefit to know that age was a predictor of medical complications alone. Interestingly, older participants were less likely to have sufficient knowledge of medical complications, even though they obtained significant sufficient knowledge regarding medical errors. In addition to older ages, unemployed individuals were associated with high medical error knowledge and low medical complication knowledge. This could further support the suggestion that older and unemployed individuals might have a more conservative grasp on medical errors.

Patients’ perceptions are, above all, complicated by other factors relating to how the physician communicates and delivers the medical information. As correspondents stated the lack of influence social media had on their general health education, physicians’ role is of importance to shift patient expectations to a more realistic outlook and provide the medical information in advance of treatment to partially prevent any emerging confusion.\(^{[34]}\) The findings of the current study reflect the need in educating the public about medical complications to balance out its knowledge level with medical error knowledge, as this would provide health care consumers and patients the ability to differentiate between the two terms and their involving contexts. As for medical errors, disclosing errors openly and truthfully will decrease the chances of physicians being litigated and further prevent an erosion of trust within the physician-patient relationship.\(^{[35,36]}\) The findings could reflect what changes could be made to benefit the primary care physicians in how they communicate with patients as they are the first line of encountering different and undiagnosed cases.

This study has certain limitations. The first limitation is that we used convenience sampling which was specific to one hospital in Riyadh, and this might have altered the generalizability of our sampling to the Saudi population. Secondly, there was no previously developed questionnaire that could have been taken as a reference; therefore, our questionnaire was self-designed based on common vignettes related to medical errors and complications. The overall result of the study could change based on the selection of vignettes; however, they display the level of patients’ knowledge regarding medical errors and complications simultaneously.

In an attempt to bridge the gap between the knowledge level of medical errors and medical complications, new research is needed due to the limitations of this study and the lack of studies conducted regarding this matter. In addition, some studies have used different definitions and terms interchangeably, thus exploring how to unify these terms would help in explaining the issue more thoroughly.

Conclusion

The study assessed the level of knowledge of medical complications and errors of patients at a tertiary hospital. The findings indicated that the level of medical error knowledge was higher than medical complication knowledge. Employment status and the level of education were predictors of the knowledge level of both medical errors and medical complications.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Key messages:

Medical errors and complications are the key concepts that define patient’s safety. A clear understanding of the two entities has been associated with positive outcomes; hence, our main objective was to investigate whether the patients have sufficient knowledge about these as this would be relevant in improving health care delivery.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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