Effect of Applying Guideline for Patients Undergoing
Plasmapheresis Outcomes at Mansoura University Hospital

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Abstract: Plasmapheresis is considered the first line of treatment choice for autoimmune disease. However, recent study shows that a major portion of patients need instructional guidelines about plasmapheresis to increase knowledge and decrease complications.

Aim of the current study: was to determine the effect of applying guideline for patients undergoing plasmapheresis outcomes.

Method: A quasi experimental research design was be utilized in this study. The study was conducted in plasmapheresis unit at blood bank building at Mansoura University Hospital. A purposive sample of participants was used over a period of 6 months who correspond to inclusion criteria. Tools used for data collection in this study consisted of three tools as the following; tool I: interviewing Questionnaire Sheet which is consist of two parts, demographic characteristic of patient and the second part is concerns with medical and surgical history of patients. Tool II: Patient’s knowledge assessment Sheet. Tool III: is complications checklist of plasmapheresis.

Results: There was a significant improvement of the knowledge of the studied patients about plasmapheresis and significant increase the awareness of the studied patients about complications of plasmapheresis procedure.

Conclusion and recommendations: it can be concluded that patient's knowledge about plasmapheresis significantly improved after implementing the health guidelines so, recommend that applying guidelines in different sitting and large communities.

Key words: Guidelines, Patient's Knowledge, Plasmapheresis.

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I. Introduction

Autoimmune diseases are the most driving reasons of death among female children and women in all age groups in the United States. One of new modalities is plasmapheresis for autoimmune disease. Plasmapheresis is fast, safe, and powerful for emergent management in critically sick patient. In critically ill patients, plasmapheresis is used to remove toxins, medications, destructive antibodies, and clotting factors from the circulation¹.

The National Institutes of Health (NIH)(2016); estimates up to 23.5 million Americans suffer from autoimmune disease and that the prevalence is rising. At American Autoimmune Related Diseases Association (AARDA) reported that 50 million Americans suffer from autoimmune disease².

Plasmapheresis or Therapeutic Plasma Exchange (TPE) is the treatment of choice for hematological, neurological, kidney and immunological diseases. Plasmapheresis is now used as a therapeutic modality in a wide range of conditions. Generally, plasmapheresis is used when a substance as a part of plasma, for example immunoglobulin, is intensely harmful and can be proficiently evacuated. Myriad conditions fall under this classification, including neurologic, metabolic, hematologic, dermatologic, rheumatologic, and renal diseases, as well as intoxications, that can be treated with plasmapheresis³.

Plasmapheresis is a relatively unfamiliar area of nursing practice. It requires a particular set of technical skills and specialized knowledge. All nurses must be appropriately qualified and trained in the procedures they regularly perform. Level of patients’ knowledge regarding plasmapheresis will effect on the incidence and severity of complications of plasmapheresis⁴.

The role of nurse in the process of plasmapheresis is various and is great in clinical, educational, inquiring and advisory. The nurse is the patient’s tutor, the consultant, the primary care provider, the educator, the administrator, the investigator and the instructor. Nurse’s main duties are maintaining and improving standards of nursing care, effective use of resources and enhancement in quality both in the life of the
individuals undergoing plasmapheresis and the delivery of health services and provide personalized, humanistic and comprehensive nursing care to plasmapheresis patients\(^4\).

**II. Significance of the Study**

Nurses play a vital role in educating patient to overcome the negative aspect of their treatment. Also, they deal with their disease with maturity and promote the maximum level of rehabilitation. Training course may decrease the psychological stress for plasmapheresis patient, increase their responsibility and their knowledge about plasmaphereses, ensure patient safety, provide appropriate care, prevention and early detection of complications, which leads to better results\(^8\).

**Aim of the study;**
The aim of this study is to determine the effect of applying guideline for patients undergoing plasmapheresis outcomes.

**Research Hypothesis;**
- Patients’ knowledge regarding plasmapheresis will be improved after guidelines implementation.
- Increase the awareness of patients to decrease occurrence of complications.

**III. Method**

1. **Research Design;**
   A quasi experimental research design was utilized in this study to assess the effect of applying guideline of patients undergoing plasmapheresis. In its simplest form it requires a pretest and posttest for a treated and comparison group\(^6\).

2. **Study Setting;**
   This study was conducted at plasmapheresis unit at blood bank center at Mansoura University Hospitals, Dakahlia, Egypt.

3. **Study Subjects;**
   It was include purposive sample of 160 patients for six months who attend to the previous mentioned hospital six days per week from 9 am to 1pm in morning shift or from 2pm to 6pm in the evening shift for who were participates in the study. It was started from the beginning of September 2017 to the end of February 2018. The patients were selected based on the following criteria: age between 20-60 years old, both sexes, patients whose undergoing plasmapheresis and agree to participate, consciousness and able to communicate.

4. **Tools;**
   All tools were developed by the investigator. Three tools were used for data collection in this study as the following:

   **Tool I: Interviewing Questionnaire Sheet:**
   It was contain two parts which aimed to collect personal and medical data about the study subjects. It was conducted in Arabic language after reviewing related literature and collected only one time before providing guidelines about plasmapheresis. This data were collected by the investigator from the patients\(^7\).

   **Part I: Demographic data of the studied patients**
   This part was assessing demographic data of the studied patients. It was consist of 8 questions including name, age, gender, educational level, residence, marital status, occupation and serial number.

   **Part II: Patient health relevant data**
   This part was concern with medical and surgical history of patients and it consists of ten questions including diagnosis, duration of disease, associated disease, relative diseased person, related degree, history of surgical operation, types of surgical operation, names of previous and current drugs used and investigations.

   **Tool II: Patient’s Knowledge about plasmapheresis interviewing questionnaire:**
   This tool was aimed to assess patient's knowledge regarding plasmapheresis procedure. After reviewing the most recent and relevant literatures and articles; this tool was constructed. It was collected in two times before and after providing guidelines which included a series of questions to elicit patient's knowledge related to plasmapheresis.
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It consisted of eleven questions including definition of plasma, definition of plasmapheresis, indications of plasmapheresis, aim of plasmapheresis, contraindications of plasmapheresis, duration and frequency of procedure, questions about nursing care before, during and after procedure and about occurrence of complications.

**Scoring system:**
Related scoring system every question was in the form of choosing the correct answer. One score for true and zero for false one

**Tool III: Complications checklist of plasmapheresis:**
It was developed to assess incidence of complications before and after applying guidelines. It was designed and used by the investigator after reviewing related literature for collected necessary data for this study.

This tool was contain 24 complications of plasmapheresis with yes or no choose such as infection, bleeding, drop in blood pressure, bruising or swelling at the needle insertion sites, seizures, excessive itching or rash, nausea and/or vomiting, vascular access haematoma, fainting, fatigue, hyperthermia, arrhythmias, shivering, dyspnoea, colic, blurred vision, dizziness, numbness around mouth and peripheral limbs, hypothermia, Joint pain, thrombocytopenia, cramps and anaphylactic reactions.

**Scoring system:**
Scoring system in the checklist sheet answer was evaluated using yes or no model key answer. One score for yes answer and zero for no. All scores were transformed into score %.

5. **Validity and reliability:**
The developed tool was tested for content-related validity by 5 experts in nursing field (2 professor and 1 assistant professor from Mansoura University and 2 physicians from the hematological unit Mansoura University Hospital). The tool was being reviewed for clarity, relevance, comprehensiveness; simplicity and applicability for implementation and the questionnaire were are modified accordingly.

The reliability of the developed tools was estimated using the Chronbach's Alpha test to measure internal consistency of the tools.

**N.B Chronbach's Alpha is an international measure of reliability which was (alpha=0.882).** Its maximum value is 1.0, which indicate highest reliability and the minimum accepted value is 0.65, below this value indicate unreliable tool.

**Chronbach's Alpha equation:**
\[
R = \frac{k(1 - \sum \sigma_i^2)}{(k-1)\sigma_y^2}
\]

Where:
- \( R \) = estimated reliability.
- \( k \) = total number of items in test.
- \( \sigma_i^2 \) = variance of each individual items.
- \( \sigma_y^2 \) = variance of the total test scores.
- \( \Sigma \) = sum of.

Interviewing Questionnaire Sheet, Patient’s Knowledge about plasmapheresis interviewing questionnaire and Complications checklist sheet of plasmapheresis procedure had proven a high reliability, Internal consistency was found to be good, Construct validity was judged to be good. In addition, content validity was found to be good.

6. **Pilot study:**
A pilot study was carried out on 10% of patients (16 patients) from the plasmapheresis unit at Mansoura University hospital to assess the clarity and the applicability of the tool, and the necessary modification was done prior to data collection. Those patients were excluded in the main study.

7. **Ethical considerations:**
The investigator obtained the required permissions from the Research Ethics Committee of Nursing faculty, Mansoura University. Oral approval for the study was attended from each participant after verbal explanation of the study nature and objective were reported to all research participants. All patients were informed about their rights to agree or disagree to participate in the study and they were permitted to leave from the research at any point of time and this will not affect their care.
8. Procedure:
1. After the proposal was approved by research ethical committee, Faculty of Nursing, Mansoura University, the investigator approached director of Mansoura University Hospitals to get permission for data collection.
2. The tool was being written in Arabic language. The investigator was filling in the questionnaire for patients who are illiterate.
3. Once the participant had enrolled in the study, the investigator contacted with the participant and collected data. The data were collected via individual interviews.
4. In each day, the potential samples were eligible for the study if they met the inclusion criteria, each participant was interviewed twice: the first time before providing health guideline (pretest) and the second time after providing health guidelines (posttest) during morning or evening shift at plasmapheresis unit six days per week over a period of 6 months from September 2017 to February 2018.
5. At the first time, the investigator introduced herself to the participant to gain patient confidence and make good communication. Then, investigator informed the participant about the purposes, method, and procedure of study. The investigator took their verbal consent if willing to participate in the study.
6. Then, every participant was interviewed by the investigator and was asked to answering the questions related to their experiences of plasmapheresis procedure. If the participant felt uncomfortable or not ready for answering the questionnaires, the investigator would not start until participant felt calm down and ready to participate.
7. Demographic characteristics and health relevant data (tool one) were completed from patient’s medical record and patient interview at the first meeting only before providing health guidelines.
8. Tool two and tool three were being obtained in two times, first time before education session (pretest). Tool two was be used to assess patient's knowledge about plasmapheresis. Tool three was be used to assess the incidence of complications during plasmapheresis procedure.
9. After that, the investigator was implement guidelines. A simple colored Arabic booklet was developed for patients related to plasmapheresis for more understanding and clarification. The educational booklet includes definition of autoimmune disease, definition of plasma, definition of plasmapheresis, aim of plasmapheresis, indication and contraindication of plasmapheresis, complication of plasmapheresis. Also, guidelines for patients undergoing plasmapheresis before, during and after the procedure.
10. In the second time, the investigator evaluate immediately their level of knowledge about all information they taken by used tool two and tool three (posttest).
11. The evaluation phase was focused on estimating the effect of the guidelines on patient's knowledge through assessing twice before and after implementing the guidelines. The time taken to assess and manage each patient was 1 hour.

9. Statistical analysis:
Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 16. Qualitative variables were presented as frequency and percentages and quantitative continuous variables were represented as mean ± SD. Chi square ($\chi^2$) was used for comparison of categorical variables, and was replaced by Fisher exact test (FET) or Mont Carlo Exact test if the expected value of any cell was less than 5. Student's t test was used for comparison of continuous quantitative variables (two groups) and one way anova (F test) was used for comparison of continuous quantitative variables (more than two groups). The difference was considered significant at $P \leq 0.05$.

IV. Results

Table (1): Distribution of demographic characteristics of the studied patients (no=160).
Table (1): Shows demographic characteristics of the studied patients. The age of the studied patients was with mean 44.99 ± 8.90 years. Nearly half of patients (48.1%) were at age 40.0 to 50.0 years, sex ratio was nearly equal, and (75.0%) of them were married. Most of the patients were secondary and university educated (46.9% and 46.2%) respectively and (52.5%) of the studied patients were from urban area. As regard occupation; (33.8%) of the patients were manual workers, (43.1%) were employee and professionals while (23.1%) were house wifes.

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<td>40-49</td>
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<td>50-60</td>
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<tr>
<td>Mean ± SD</td>
<td>44.99 ± 8.90 years</td>
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<tr>
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<td>49.4</td>
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Females 81  50.6

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<td>House wife</td>
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</table>

**Figure (1): Knowledge level of the studied patients before and after health education guidelines**

Figure (2): Shows the knowledge level of the studied patients before and after health education guidelines. There was a significant improvement of the level of the patient's knowledge after health education guidelines. The percentage of good knowledge progressed from 10.6% before health education guidelines to 66.9% after health education guidelines.

![Figure 2: Knowledge level of the studied patients before and after health education guidelines](image)

\[ \chi^2 = 125.19, P < 0.001 \]

**Table (2): Distribution of complications reported by the studied patients before and after health education guidelines (n=160).**

Table (2) Displays the complications was reported by the studied patients due to plasmapheresis procedure before and after health education guidelines. There was a significant increase of the percentages of the most reported complication after health education guidelines (fainting, hypotension, rash, itching, fatigue and tired, cramps, dyspnea, numbness of limbs and around mouth, feeling cold, joint pain) (p<0.001, p=0.001, p=0.002, p=0.005, p<0.001, p<0.002, p<0.001, p<0.001, p<0.001, p<0.001) respectively and this reflect the effectiveness of the health education guidelines program.

<table>
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<th>Significance test</th>
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<td>1-Fainting</td>
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<td>31</td>
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<td>2-Bleeding</td>
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<td>12</td>
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<tr>
<td>3-Hypotension</td>
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<td>48.1</td>
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<tr>
<td>4-Needle bruises</td>
<td>8</td>
<td>5.0</td>
<td>3</td>
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<tr>
<td>5-Convulsions</td>
<td>6</td>
<td>3.8</td>
<td>11</td>
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<tr>
<td>6-Nausea</td>
<td>33</td>
<td>20.6</td>
<td>43</td>
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<tr>
<td>7-Vomiting</td>
<td>34</td>
<td>21.2</td>
<td>30</td>
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<tr>
<td>8-Rash</td>
<td>14</td>
<td>8.8</td>
<td>34</td>
</tr>
<tr>
<td>9-Itching</td>
<td>32</td>
<td>20.0</td>
<td>54</td>
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### V. Discussion

Plasmapheresis procedure is an advanced, established, safe, rapid, and effective extracorporeal procedure which used to remove toxins, destructive antibodies, medications, and clotting factors from the circulation. The most common complications of this procedure are: hypotension, hypocalcemia, hypokalemia, numbness of the extremities, muscle cramps, a metallic taste in the mouth, bacterial infections, allergic reactions and severe suppression of the immune system. Nurse’s main duties are maintaining and improving standards of nursing care, effective use of resources and enhancement in quality both in the life of the individuals undergoing plasmapheresis and the delivery of health services and provide personalized, humanistic and comprehensive nursing care to plasmapheresis patients. Therefore, the current study concentrated on evaluates the effect of applying guideline for patients undergoing plasmapheresis outcomes at Mansoura University Hospital.

### 1- Demographic characteristics of studied patients:

The demographic background of the present study showed that nearly half of studied patients were in the fourth decade. This can be explained by the fact that as with increasing in age, individuals are at risk for autoimmune disease. In this respect Yeh et al., Ahmed et al., who reported that half of their studied patients were among the fourth decade. Contrast to Batocchi et al., who revealed that more than one third of studied patients were more than 60 years old. This difference between current study and other findings may be due to difference in sample characteristics in every study.

In relation to sex, it is found that; ratio of the studied group was nearly equal. On contrary to other studies, who reported that about two third of the study subject showed that more than two third of their studied sample were males. This difference may be due to the difference of the awareness between female and male among health status depending on the difference of regional area.

In the present study, two third of studied patients were married. This is in agreement with other studies done in Ethiopia by Expert Panel on Detection et al., who reported that about two third of the study subject were married.

Concerning level of education, most of studied sample were secondary school and highly educated. This in contrast with other studies by Keesey, who reported that one third of studied patients were illiterate. As regard occupation; in the current study revealed that more than one third of studied group were employee. This finding is not coinciding with the study done by Yeh et al., who found that few of studied patients were government employee and nearly one third were housewives. This may explained that the education and employment increase the chance of exposure to stress which lead to reduce the human immunity.

With regard to occupation, more than one third of studied patients were employee. It can explained by the fact of most of studied patients were secondary school and highly educated and this increase the opportunity of getting job. This was in contrast of the study done by Friedman et al., who stated that nearly one third of studied patients were unemployed and house wife. This can interpreted due to old age with the course of disease.

### 2- Medical history of the studied patients:

The present study revealed that Myasthenia Gravis (MG) is the most commonly founded diagnosis followed by Gallian Barrie syndrome (GBS). These findings are in agreement with the findings of Yeh et al., who found that more than two third of their studied sample were suffering myasthenia gravis. Contrary to the results of the study by Kruzik, mentioned that, patients diagnosed with GBS represent two third of total studied patients in their study, whereas MG represent...
nearly one third of total studied patients. This can be explained by continuous stressful life events which are risk factors for lowering immunity system of individual and therefore exposure to (MG) and (GBS).

Additionally, hypertension and DM represent high percentage of studied sample than other common associated diseases. Our results in contrary with Finkelstein et al. (21), who reported that all of his studied group were free of medical disorders. Difference may be attributed to increase in age that made people more liable to chronic diseases as DM and hypertension. In the light of the above point, it is found that antihypertensive drug used more than half of the studied sample followed by hypoglycemic drugs which represent more than one third from all study groups.

3- Knowledge before and after health education guidelines:

Teaching of patient plays a major role in empowering plasmapheresis adult patients. Teaching patient using a combination of methods as teaching, counseling and behavior modification, about their disease, procedure and side effect management can enhance coping mechanisms, improve patients’ knowledge, health behaviors, and improve clinical outcomes in adult patients with a variety of diseases. Patients who understand their disease and treatment have greater compliance with therapy, which translates into better outcomes Friedman et al. (22).

The present study revealed that about two third of studied patients had poor knowledge about their disease, plasmapheresis procedure and its side effect. This may be explained by the lack of attention of nurses to teach patients about plasmapheresis concerns. Furthermore, the present study revealed that there was statistically significant difference in adult knowledge regarding their disease, plasmapheresis procedure and its complication after applying guidelines. This can illustrated by the fact that teaching patients about their disease, treatment, and side effect can enhance coping mechanisms and improve patient's knowledge and may be due to the level of education which were secondary followed by university.

This result is supported by a study done by Couler et al. (23), who documented that structured educational guideline has a beneficial impact in improving the knowledge for the patients. Also this is in the harmony with the study done by Aldcroft et al. (24), who noted that health education guidelines increase patient’s knowledge and gives them chance to expect what’s going to happen and when it’s going to happen.

This finding come in line with the study done by Ahmed et al. (25), who reported that there is improved in knowledge associated with the educational interventions. Also, Yeh et al. (26), found that planned teaching program was effective in improving patient knowledge and reduced confusion regarding plasmapheresis. In addition, studies by Lee et al. (27), emphasized that health education programs have beneficial effects on patient knowledge and guide professionals to implementing health educational programs, as an established practice, at the hospitals.

Current evidence highlights that applying education program helps improve knowledge and self-care among patients. Such educational programs should be adopted in clinical settings to enhance knowledge and self-care behaviors Tawalbeh (27). In the present study knowledge about indications and contraindication, the specified session’s numbers and the duration of the plasmapheresis procedure significantly improved, as the percentage of correct answer increased after health educational guidelines. These findings goes well together with Basic-Jukic et al. (28), who noted that educational programs impact the patient’s knowledge regarding their own health problem.

In addition, studies by Zanaboni et al. (29), Lilholt et al. (30), documented that after planned health educational guidelines the majority of studied patients had excellent level of knowledge in posttest. Studied patients had shown improved knowledge and awareness of their symptoms and health status, and qualitative analyses indicate positive effects on self-management, psychological condition, and coping ability. Patient education is the belief that one has a role in self-managing care to manage one’s condition, maintain functioning, collaborate with health care providers, and access appropriate care Hibbard et al. (31).

The findings of the current study demonstrate significant improvement of the patient’s knowledge regarding the plasmapheresis procedure with apparent increase in percentage of correct answer after health education guidelines. These findings goes well together with Sis Sis Çelik et al. (32), whose found that planned health education guidelines about health problem and its related therapeutic intervention increase patient’s awareness, reduced patients negative beliefs and enhanced their quality of life.

4- Complications reported by the studied patients:

Plasmapheresis is a safe procedure with the majority of reactions and complications being mild, easily treated, and of limited duration. The frequency of complications was strongly associated with plasmapheresis procedure and the type of replacement fluid. This could well have been due to the hypo-oncotic effect, which produces an albumin concentration much lower than the total protein concentration Winters (6).

In this study; patients awareness of their complications significantly increase after the application of health educational guidelines, this may attributed to the underlying diagnosis, method of plasma separation, and
the subjective nature of complications. In our results, found that the most common reported complications were hypotension followed by dyspnea. In the same line, study done by Yeh et al. (10), Yeh et al. (10) noted that the frequency of hypotension was higher in cases of chronic inflammatory neuropathy compared to the other illness categories. In the same direction Rizvi et al. (33) reported that the most common complication were hypotension, which occurred in nearly half of patients, followed by bleeding which more than one third of studied patients. This can interpret by occurrence of vasovagal episodes, hypo-oncotic fluid replacement, delayed or inadequate volume replacement.

On the other hand, prospective study clarified by Shenin et al. (7) regarding examination the rate of the plasmapheresis complications found that the complication were minor and well tolerated and the most common complications were fever followed by urticaria followed by and hypocalcemic symptoms. The difference of complication occurrence may be due to according to the diseases.

According to Weinstein (14) reported that the most common reaction seen are paresthesias related to hypocalcaemia resulting from the use of citrate anticoagulant. This is in agreement with other study by Winters (6) stated that the most common complication is paresthesia related to hypocalcaemia. On contract, the findings of Rizvi et al. (33) reported that, bronchopneumonia and vascular access related complications are more prevalent among plasmapheresis patients. Also, other studies were done by Karaca et al. (36), Tombak et al. (36) show that hypocalcaemia and anemia were the most common complication that happened after plasmapheresis procedure. Educational guideline was found to be valuable and transferable to the everyday clinical practice. A wide range of plasmapheresis complications were less apparent for patients and continuously linked by the patient to disease process.

As regarding to relation between patient's characteristics and level of knowledge our study indicated that, a significant positive relation between increased knowledge score in relation to age and level of education, this may attributed to increased awareness of problem, and appropriate perception of medical advice. This finding was congruent with Solliman et al. (37), Shrestha et al. (38) reported significantly high knowledge scores in educated adult patients. As the majority of patients with literacy problems are unable to follow the prescription directions. Patients are more likely to understand prescription directions, and follow them correctly, when they are literate persons Shrestha et al. (38). Thus, continued effective health education guideline to plasmapheresis patients, is expected to bring about greater knowledge score and awareness related to plasmapheresis procedure and its related complications.

VI. Conclusion

Based on the present study findings, it can be concluded that guidelines of patients undergoing plasmapheresis significantly improved patient's knowledge about plasmapheresis. It could be seen that, there was significant improvement of the total knowledge score from above one third (19.3±4.09) before health education guidelines and progressed to almost of studied group (50.65±4.09) after instructions. This study also revealed that, was a significant increase of the percentage of the most reported complications after health education guidelines and this reflect the effectiveness of the health education program.

Limitation of the study

- Unsuitable environment as interview were held in the plasmapheresis unit where there were too much noise, movement and distraction.
- Some interviews were deleted due to uncompleted number of plasma in blood bank for the patient, due to feverish of the patients, due to high or low blood pressure of the patients or due to intubating the patient in ICU.
- Some patients were blind due to muscle weakness or weak hearing due to aging which make the interview hard.

VII. Recommendations

Based on the result of the present study, the following recommendations are suggested:

- A simplified and comprehensive educational booklet should be introduced and clearly explained to the plasmapheresis patients.
- Administrators should create policies and plans for providing continuous instructions to the plasmapheresis patients.
- Periodic evaluation of patient's knowledge is essential to determine the needed for instructions program.
- Further researches should be applied to evaluate the impact of instructional booklet on different geographical regions.