Impact of self-instruction manual-based training of family caregivers of neurosurgery patients on their knowledge and care practices – A randomized controlled trial

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ABSTRACT

Background: Family caregivers of operated neurosurgery patients function as informal extensions of the health system. But they are untrained and unprepared for their new role. It has been felt that their problems related to care provision can be resolved by appropriate training. Aim: This study aimed to compare the impact of self-instruction manual-based training of family caregivers of operated neurosurgery patients on their knowledge regarding care provision and care practices. Setting: Tertiary care hospital setting located in North India. Design: Randomized controlled trial. Materials and Methods: A randomized controlled trial was done among the operated neurosurgery patients and their caregiver dyads (n = 90). They were randomly allocated to receive either self-instruction manual and one-to-one training (TP1) or self-instruction manual only (TP2). Block randomization method was used. Sequentially numbered sealed envelope was used for allocation concealment. Monthly follow-up was done for 3 months. The primary outcome measure was knowledge gain of the caregivers. Statistical Analysis Used: Chi-square test, Student's t-test, paired t-test, repeated measures analysis of variance, and Bonferroni’s correction were used. Results: The attrition rate was 15.5%. Intention-to-treat analysis was followed. Caregivers in the TP1 group had significant knowledge gain (95% confidence interval of mean difference 9.4–14.5, P < 0.05). The number of caregivers who had followed correct caregiving practices was significantly more in the TP1 group. Conclusion: Training of caregivers by providing information along with one-to-one training is an effective strategy for improving the knowledge and skills of caregivers regarding care provision of the operated neurosurgery patients.

Keywords: Bedridden, caregiver, neurosurgery, randomized controlled trial, training

Introduction

A large proportion of neurosurgery patients develop physical, cognitive, and emotional impairments which usually make them dependent even for their Activities of Daily Living (ADL). They experience a variable period of convalescence. This results in serious compromise in the quality of remaining lives of the affected people.

Unlike the developed and Western countries that have well-developed posttraumatic rehabilitation centers and organizations for the purpose, in India, the burden of caring such a patient falls on the immediate family members. They ultimately provide long-term assistance and support for the survivors for months or years together, but they are usually untrained and unprepared to new roles and responsibilities and lack basic knowledge about care provision. Effective discharge planning is also impeded by gaps in communication between the doctors.

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and patients’ caregivers such as poor discharge advices in both written and verbal form.\textsuperscript{[7]}

As of now, in India, the family members are informally involved in caregiving, and there is no system of simplified and standardized instructions given systematically to caregivers.\textsuperscript{[3-5]} It has often been felt that many of the problems related to care provision can be resolved at home level itself by the family caregivers if they are appropriately trained during their hospital stay and also doing follow-up training at their home.\textsuperscript{[6]} It is believed that such an approach helps in increasing the basic knowledge and practices of the caregivers regarding care provision.\textsuperscript{[11]} This will make them confident to perform their role and eventually improve the quality of care given to the patients. Our study was an attempt to assess the impact of providing self-instruction manual and one-to-one training to the caregivers on their knowledge and care practices.

Materials and Methods

A randomized controlled trial was conducted between January 2011 and June 2012 among the operated neurosurgery patients and their caregivers. The study was registered in ICMR trial register on 27.07.2011 (CTRI/2011/07/001921). Ethical clearance was obtained from the ethics committee of PGIMER, Chandigarh, for the trial. A sample size of 36 patients and caregiver dyads in each group (TP1 = self-instruction manual + one-to-one training and TP2 = self-instruction manual only) was decided at an alpha error of 0.05 and power 80% with the assumption of mean difference of 2 points in knowledge score between the groups after intervention. However, to overcome the problem of dropouts, 45 patient and caregiver dyads in each group were recruited.

Recruitment of the cases was done using block randomization method (block size of four was used) by the faculty not involved in the study. The randomization sequence was generated using MS Excel software and it was sealed in a sequentially numbered envelope to maintain the allocation concealment. Assignment of the subject to a particular group was done by the investigator based on the sealed envelope.

Written informed consent was obtained from all the participants. For our study purpose, the operated neurosurgery patients included any patients who got operated in the Department of Neurosurgery at PGIMER, Chandigarh, during the reference period (January 2010–December 2011). All neurosurgery patients were assessed for their dependency in their ADL by KATZ index of ADL.\textsuperscript{[12]} Patients with KATZ index score ranging from 1 to 5, irrespective of their variability in diagnosis and type of treatment received, were included in the study; this made the group homogeneous with respect to their dependency in ADL, and patients with Katz index score = 6 (fully independent) were excluded as they are fully independent to carry out their ADL. Patients with all their family members being illiterates (not able to read the manual) were excluded. For feasibility issues, patients residing out of Tricity (Chandigarh/Panchkula/Mohali) were also excluded.

The self-instruction manual was carefully designed based on the research teams’ previous experiences in this field, group discussions, and expert opinion. Caregivers’ needs were assessed through the multiple focus group discussions incorporated into the manual. The manual had comprehensively covered the needs of family caregivers of bedridden patients such as bedsore prevention, contracture prevention, nasogastric (NG) tube care, urinary catheter care, tracheostomy care, time management techniques, and stress reduction techniques. The manual was finalized and translated into local language (Hindi) after pretesting. After the completion of the research project, the manual was eventually published as a textbook in local language, that is, Hindi.\textsuperscript{[13]}

The first group (TP1) received one-to-one training and demonstration of necessary procedures, whereas the second group (TP2) received routine care with self-instruction manual only. The purpose of the study was explained to the patient/caregivers, After taking their consent, patient caregiver dyads of TP1 group were provided manual-based training as per the need assessed case-by-case basis, that is, as per the status of the patients’ ADL as well as the status and quality of the existing caregiving practices. For individual cases, suitable component of intervention package from the manual was selected on the basis of assessment of the condition of the patient and caregiver. The required procedure was demonstrated on one-to-one basis by the investigator. Family members other than the primary caregiver were also requested to read the relevant part from the manual. They were asked to seek any clarification as per their need. Caregivers in the TP2 group were given routine advice and asked to follow the required instructions in the self-instruction manual.

The existing procedures being followed by the caregivers for giving care to the operated neurosurgery patients suggested by the treating physician/nurse were compared with the developed procedures for the study. It was clarified to the family and the patients that they were free to continue with the advice or treatment given by their treating physician/nurse. The same was documented. The study protocol was discussed with the treating physician/nurse. No pharmacological advice or prescription was advised by the researcher to the participants.

After intervention, once-a-month follow-up visit for 3 months was done for both the groups. Follow-up visits were done in the patients’ home. During follow-up visits, the disability status of the patients was evaluated and the caregivers were observed for their correct care practices; if any discrepancy was found, it was corrected and their queries were clarified. Feedback was taken in each visit and the details were noted on the follow-up pro forma.

The primary outcome variable was knowledge of the caregivers regarding care provision. The questionnaire to assess the knowledge of the caregivers about the care provision to the operated neurosurgery patients was designed by the research team. Face validity and content validity of the questionnaire were done. The reliability of the questionnaire was checked by test–retest method (Pearson’s correlation coefficient = 0.659,

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Care practices of the caregivers were measured by observation using the checklist made by the research team based on the self-instruction manual.

Blinding was not followed in the implementation of intervention and in outcome assessment. Intention-to-treat principle was followed for analysis. Data were entered and analyzed in SPSS version 16.0. Descriptive analysis such as percentages was calculated for the categorical variables, and mean and standard deviation were computed for quantitative variables. Chi-square test was used to compare the proportions, and independent t-test was used to compare the means between the groups. Repeated measures analysis of variance (ANOVA) was used to test the difference in means calculated at multiple time points (longitudinal data). Bonferroni's correction was done for all pair-wise comparisons. Normality of the data was checked before using any hypothesis test, and wherever data seemed to be skewed, appropriate nonparametric test (Mann–Whitney U-test and Wilcoxon rank-sum test) was used.

Results

Overall, 110 eligible patients were referred from neurosurgery ward and outpatient department; of these, 20 patients were excluded for the reasons mentioned in Figure 1. Thus, 90 patients were enrolled in the study. After randomization, 45 patients were allocated to TP2 (self-instruction manual only) and 45 patients were allocated to TP1 (self-instruction manual + one-to-one training). Background variables of neurosurgery patients and their caregivers were equally distributed between the groups which made the groups comparable.

A total of 18 (40%) patients were dropped out in TP1; of these, 5 (11.1%) were lost to follow-up and follow-up was intentionally stopped to 10 (22.2%) patients since they became fully independent, that is, the patients achieved the KATZ index of ADL score of 6 which indicated that the patients were fully independent and do not require any caregiver’s help to perform their ADL, and 3 (6.7%) patients died.

A total of 23 (51%) patients were dropped out in TP2; of these, 9 (20%) patients were lost to follow-up and follow-up was intentionally stopped to 11 (24.4%) patients since they became fully independent, that is, the patients achieved the KATZ score of 6 which indicated that they were fully independent and do not require any caregiver’s help to perform their ADL, and 3 (6.7) patients died. Finally, at the end of third month, there were 27 (60%) and 22 (49%) and the patients completed the study period in TP1 and 2, respectively.

As can be seen from Figure 2, at baseline, there was no significant difference in the mean score in the knowledge regarding general care provision between groups TP1 (one-to-one + SIM) and TP2 (SIM only), but there was a significant increase in the mean knowledge score in TP1 than TP2 across the study period, that is, in the first, second, and third month follow-up visits. Independent sample t-test adjusted for all pair-wise comparisons using Bonferroni’s correction was done as a test of significance.

Within the group, analysis showed that there was significant increase in the mean knowledge score of the caregivers across the study period (all three follow-ups) when compared with the baseline for both the groups [Table 1]. However, in the group TP2, at third month, the follow-up score was not significantly higher when compared with the baseline. Repeated measures ANOVA
with Greenhouse–Geisser correction also determined that there is an overall significant difference in the mean score between different time points ($P = 0.001$ for TP1 and $P = 0.09$ for TP2).

Care practices were assessed using a checklist prepared by the researcher. Various aspects of care practices such as correct method of position change, skin care, recommended exercises, care during NG tube feeding, tracheostomy tube care, urinary catheter care, and hand washing methods were assessed. Table 2 compares the proper/correct care practices of caregivers in both the groups (TP1 and TP2) at baseline and at third month. In almost all the aspects of care practices, except NG tube feeding and following correct principles of exercises, significantly higher number of caregivers of TP1 performed correct care practices at the end of third month.

### Discussion

This study was conducted to assess the impact of training family caregivers of operated neurosurgery patients by one-to-one demonstration with the self-instruction manual on their knowledge and care practices. Eligible cases were randomized into two groups. Group TP1 received one-to-one training and demonstration of each procedure along with the self-instruction manual, whereas group TP2 received only self-instruction manual with routine care.

We found that there was a favorable effect of the training on the knowledge of the caregivers regarding general aspects of caregiving which was supported by various studies. In our study, within the group analysis showed that the knowledge increased in both the groups across the study period. However, the increase in knowledge is much more and consistent among the caregivers in TP1 than TP2. This shows that providing manual alone will also increase the knowledge over time, but the increase will be significantly more and consistent if the manual is provided with one-to-one demonstrations.

While assessing the knowledge regarding specific components of caregiving, there was a significant increase in knowledge regarding bedsore prevention and contracture prevention among caregivers of TP1 than the caregivers of TP2. But similar difference was not found in the knowledge regarding NG tube care and urinary catheter care. This could be due to the fact that the caregivers in TP2 ended up giving importance to the denotative problems only, that is, the ones that are exclusively observable like in the case of special tubes (NG tube, urinary catheter, etc.) and hence learn only the concerned part from the manual. Caregivers with only manual and routine advice failed to give importance to basic problems such as bedsore prevention and contracture prevention. This means that unless his or her patient gets bedsore, they did not care about that issue. This behavior of adult learning was discussed by Knowles; he says that adult learners are problem-centered, that is, they prefer to learn what they need to know at the time they need to know it, and apply their learning to a real-life situation. Thus,

| Table 1: Change in the mean knowledge score of the caregivers within the groups across the study period with the baseline |
|----------------------------------|-----------------|-------------|--------------|--------------|
| Group | Time period | Mean difference (change in mean) | $P$-value* | 95% CI of the mean difference |
|-------|-------------|-------------------------------|------------|----------------|
| TP1   | Baseline vs | First visit: $-5.2$ | 0.001      | $-7.6$, $-2.9$ |
|       |             | Second visit: $-10$          | 0.001      | $-12.5$, $-7.5$ |
|       |             | Third visit: $-11.5$         | 0.001      | $-13.8$, $-9.1$ |
| TP2   | Baseline vs | First visit: $-1.5$          | 0.036      | $-2.9$, $-0.06$ |
|       |             | Second visit: $-2.0$         | 0.005      | $-3.6$, $-0.52$ |
|       |             | Third visit: $-1.7$          | 0.219      | $-3.9$, $0.525$ |

CI: Confidence interval. *$P$-test with Bonferroni's corrected $P$-value for pair-wise comparisons, Bold means $P$-value <0.05 is significant

| Table 2: Comparison of the care practices of caregivers in both the groups (TP1 and TP2) at baseline and end line |
|---------------------------------------------------------------|-----------------|-----------------|------------|
| Care practices                                               | Group | Baseline (n1=45, n2=45) | $P$-value | Third month (n1=22, n2=27) | $P$-value |
|----------------------------------------------------------------|-------|-----------------|------------|-----------------|------------|
| Correct method of position change                            | TP1   | 4 (41)          | 0.244      | 27 (27)         | 0.002     |
|                                                              | TP2   | 7 (40)          |            | 5 (19)          |            |
| Provides skin care correctly                                 | TP1   | 5 (41)          | 0.735      | 26 (27)         | 0.01      |
|                                                              | TP2   | 5 (41)          |            | 4 (20)          |            |
| Performs exercises                                           | TP1   | 7 (41)          | 0.775      | 24 (27)         | 0.01      |
|                                                              | TP2   | 8 (41)          |            | 5 (20)          |            |
| Correct principles of exercises                              | TP1   | 0 (7)           | NA         | 4 (7)           | 0.66*     |
|                                                              | TP2   | 0 (8)           |            | 2 (5)           |            |
| Provides NG tube feeding correctly                           | TP1   | 16 (37)         | 0.732      | 9 (9)           | 0.06*     |
|                                                              | TP2   | 12 (33)         |            | 4 (7)           |            |
| Tracheostomy care correctly                                  | TP1   | 0 (26)          | NA         | 12 (18)         | 0.02*     |
|                                                              | TP2   | 0 (23)          |            | 0 (4)           |            |
| Urinary catheter care correctly                              | TP1   | 0 (38)          | 0.233*     | 19 (19)         | 0.01      |
|                                                              | TP2   | 2 (26)          |            | 3 (18)          |            |
| Hand washing correctly                                       | TP1   | 4 (45)          | 0.519      | 16 (27)         | 0.02      |
|                                                              | TP2   | 7 (45)          |            | 6 (22)          |            |

n1=No. of participants in TP1, n2=No. of participants in TP2, number indicating the caregivers following correct/proper practices. Figures in ( ) represent the valid cases for different parameters of care practices in the concerned group across the study period NG: Nasogastric. *$P$-value of Fisher's exact test, Bold means $P$-value <0.05 is significant
family caregivers have the tendency to focus on basic physical care and visible care problems such as NG, Foley, and tracheal tube care. Another study done by Hung et al. also supported our finding in which it is reported that the rates of correctly performing the preventive tasks are very low than that the tasks related to tube care. This shows that most of the caregivers were mostly unaware regarding the practices related to prevention of bedsore and contracture.

We found that following the intervention, the number of caregivers performing their tasks such as ensuring correct position, position change, and skin care properly was improved more in TP1 rather than TP 2. This significant difference was observed from the first month onward following the intervention. This holds true except for procedure such as tracheostomy tube care. In providing tracheostomy care, a significant improvement appeared only at the third month after the intervention. This shows that providing tracheostomy care is relatively a tough skill to be acquired by the caregivers, but long-term regular training will be useful for them to master the skill. The majority of neurosurgical patients are tracheostomized to facilitate a long-term mechanical ventilator support. These patients are discharged with tracheostomy in situ. Such patients need periodical suctioning which if not done properly may be quite devastating for the patients. At times, it may be life-threatening. Thus, the caregivers need to be provided with special training for procedures such as tracheostomy care.

Our study findings have to be interpreted cautiously as there might be chance of information bias as blinding was not done in our study since it was a training-based intervention and not a pharmacological trial where placebo could be tried. Blinding in outcome assessment was also not done due to feasibility issues and also there was higher attrition in our study. The heterogeneity of the study population (operated neurosurgery patients) due to their difference in disease conditions and treatment received might also have affected the study results. However, we included patients based on KATZ index of ADL which made our group homogeneous with respect to their dependency in ADL. Proper application of randomization procedure and allocation concealment could be considered as the strengths of our study.

Conclusion

Hence, the study demonstrated that the training of the caregivers of the operated neurosurgery patients through self-instruction manual (consisting of standard operating procedures for all the care practices to be followed at home) along with one-to-one demonstrations of all the skills required for them by involving nurses/paramedical personnel at the hospital and follow-up visits at their home after their discharge at regular intervals for 3 months significantly improved the knowledge and caregiving skills of the caregiver to a great extent. This is an effective strategy to improve the quality of care of the operated neurosurgery patients. It empowered the caregivers to perform their role effectively.

To conclude, nursing care is a professional work. Family members do this work because of moral responsibility to care their beloved. The concept of caregiving and creation of a cadre of caregivers is the need of the time. While in the developed countries education programs to increase the skills and confidence of caregivers are a defined concept, in our country the concept is in naive stage only. Professional training can solve the purpose of home-based care for disabled by training family caregivers, and a cadre of professional caregivers can be built to tackle the increasing demand of family caregiving due to increasing threat of noncommunicable diseases and aging care.

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Conflicts of interest
There are no conflicts of interest.

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