EFFECT OF ALOEVERA GEL VERSUS OLIVE OIL ON PREVENTION OF PRESSURE ULCERS

A

Synopsis

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INTRODUCTION

The skin integrity generally describes the health of the skin and it is very much important to maintain the skin integrity in bed ridden patients. If the skin integrity is not maintained there will be breakage of skin continuity and development of wound / pressure ulcers.

Pressure ulcers among dependent patients or critically ill patients are a major health concern globally.[i] Due to continuous pressure on the skin mainly on the bony prominences results in development of pressure ulcer because the pressure reduces the blood flow and causes injury.

The pressure ulcers are also known as pressure injuries, decubitus ulcers and bed sores. The pressure ulcers are the result of continued pressure on the skin which results in breakdown of skin integrity. There are various factors which affects the skin integrity, i.e. malnutrition, dehydration, impaired mobility, illness, infection, advance age, friction, pressure, moisture etc. which can be assessed with the help of Braden scale and Norton scale.[ii]

A pressure ulcer can result in an open ulcer as well as pressure injury with intact skin. The pressure ulcers often affect the bone bumps like the sacrum, bumps of ASIS, Heels, trochanter, occipital and shoulder area, and rarely affect the nose, ears and lips.[iii] It also increases the length of hospital stay and treatment cost and also demands more care and also results in high mortality.[iv] It is very important to distinguish the pressure ulcers from other differential diagnosis (diabetic foot ulcer, venous leg ulcers, etc.).[v]

According to the reports of Emergency Care Research Centre of England, the risk of mortality in patients with pressure ulcers is 2-6 times more than the other patients.[vi] It was reported that 6.1 million patients each year had pressure ulcers in critical care units.[vii] The National Pressure Ulcer Advisory Panel (NPUAP) reported the incidence ranges from 0.4 percent to 38 percent in hospitals, from 2.2 percent to 23.9 percent in skilled nursing facilities, and from 0 percent to 17 percent for home health agencies.[viii] A study conducted by Chauhan *et al.*(2005) reported the 4.94% incidence rate of pressure ulcers in the Indian settings.[ix]

Pressure ulcers are the challenge in the quality treatment of the admitted patients. In effective treatment of the illnesses, preventive measures of pressure ulcers should be opted. Preventive measures of pressure ulcer in accordance with the European Pressure Ulcer Advisory Panel (EPUAP) and National Pressure Ulcer Advisory Panel (NPUAP) 2014 include: Pressure ulcer risk

assessment, assessment of skin and skin care, proper nutrition, repositioning, the use of support surface to lower the pressure and patient education on prevention and applying lotions. [x,xi,xii, xiii]

Various studies have shown the various methods of treatment and prevention of pressure ulcers, i.e. application of olive oil, coconut oil, use of hydro-colloid coating and use of sheepskin, etc. [6,xiv, xv, xvi, xvii]

Pressure ulcers are classified into four stages. In stage one there is redness on the skin that look like a red spot there is no breakdown of the skin and the area will be warm and inflamed. In stage two a superficial wound may develop and skin continuity is disrupted. In stage three skin and flesh under the skin is gone and wound is deeper than stage two. In stage four all the layers of the skin are involved and wound is deeper approaching to the bone.

Aloe Vera is a medicinal plant which contains 20 minerals, 20 amino acids, vitamins and water. In a study it was reported that use of aloe vera inhibits thromboxane (wound healing inhibitor), which helps in better, fast healing and reduces the inflammation.[xviii,xix]

The magnesium lactate present in the aloe vera reduces the itching and irritation to the skin by preventing the histaminic reaction.[xx] And the muco-polysaccharides along with amino acids and zinc in *aloe vera* helps in maintaining skin integrity, retain its moisture, reduce erythema and help prevent skin ulcers. [xxi] Aloe vera is a natural antimicrobial, antiviral, antibacterial, and antifungal. It was reported by previous studies that that use of aloe vera has goof effect in treating the wounds caused by psoriasis, mouth ulcers, diabetic ulcers herpes and bed sores.[xxii]

Zahra Abbas et al reported that the daily usage of topical Olive oil has been an effective way in promoting the skin of preterm infants and it has reduced the risk of dermatitis among them. The olive oil is composed of 98% triglycerides, including predominantly monosaturated oleic acid which has been probe to be essential for skin maintenance and this may accelerate the recovery and healing process of wound. The role of oleic acid is a key feature within the reconstruction of cell membranes providing higher smoothness to the dermis by restoring skin humidity levels, thus moisturizing the skin and providing it with elasticity.

A study finding showed that aloe vera gel dressing and Olive oil application was effective in healing of pressure ulcers in the patients, as a complementary therapy in healing of pressure ulcers in bedridden patients without any complications.[xxiii]

NEED FOR THE STUDY

Pressure ulcers are the major health concern in hospitalized patients worldwide. The pressure ulcers are caused by mainly continous sustained pressure on a particular area which abrupt the blood supply and results in tissue damage. There are many other contributing factors, i.e. friction, poor personal hygiene, prolong immobilization, etc. which results in development of pressure ulcers. When the pressure ulcers develops they increase the demand of nursing care up to 50% .

Various studies have reported the increased mortality rate with pressure ulcers.[xxiv] Russo CA, Elixhauser A. reported in Healthcare Cost and Utilization Project (HCUP) that the cost of treatment further increased after the development of pressure ulcers.[xxv]

It is important to maintain the skin integrity. Skin care routine includes the best possible nursing practices. Early healing is required for patients suffering from the pressure ulcers.

Aloe vera is an anti-bacterial, anti-inflammatory plant with the healing properties which also provides a soothing effect. The application of aloe vera gel in patients with pressure ulcers improves the skin integrity, allows the early healing and also prevents the disruption of skin.

An experimental study conducted by Singh R (2020), showed that the application of aloe vera gel had a positive impact on healing of pressure ulcer and prevention of pressure ulcers in hospitalized patients.[23]

Hekmatpou D, *et al.* (2018) reported that the use of aloe vera in hospitalized patients who were immobile at the time of study has an good impact on prevention of pressure ulcers. As the regular application of aloe vera gel helps to prevent the rise of temperature, redness, pain and swelling in pressure ulcers prone areas.[22]

Similarly it was observed by the Zanaty M M, *et al.* (2017), that the use of aloe vera cream was an effective strategy in the treatment and management of pressure ulcers. The aloe vera stimulates and accelerates the healing process as well as it decreases the cost and risk of treatment which also promotes the early healing.[xxvi]

Examining the patient's skin cleanliness, adequate eating, changing positions, using a pressure relief mattress, and avoiding skin injury are the most commonly used measures to prevent pressure ulcers. Despite these efforts, many patients continue to suffer with Pressure ulcers.[36]

Essential fatty acids, such as mepentol, corpitol, and linovera, are now one of the most extensively utilised products for the prevention of Pressure Ulcers in affluent countries. Olive oil, which is more available and less expensive than HOFA, is one of the alternatives to these chemicals. Olive oil is one of the medicinal plants that have drawn the attention of many researchers due to its simple and numerous healing properties. Olive oil contains the important fatty acids oleic acid, linoleic acid, phytosterol, and squalene, which help to hydrate, protect, and regenerate the skin. Olive oil, on the other hand, has antibacterial, anti-inflammatory, and antioxidant chemicals that cause tissue covering and hence speed wound healing. Studies showed that topical use of olive oil in the prevention of Pressure Ulcers is as effective as HOFA solutions.[36]

The combination of olive oil and aloe vera has been demonstrated in tests to improve skin lesions caused by sulphur mustard, atopic dermatitis, and chronic wounds. Therefore, it is conceivable that this combination could also be helpful for the prevention and control of Pressure Ulcers. [36]

The prevention and control of PUs is one of the most important priorities of any country's health-care system, and because herbal compounds have a positive effect on wound control, are inexpensive, and have few side effects, the current study aims to compare the common methods of preventing PUs with olive oil and aloe vera.[36]

Thus, from the previous studies it was observed that the application of aloe vera and olive oil promotes the early healing and also prevent the development of pressure ulcers in patients. The researcher during their clinical postings has assessed the prevalence of pressure ulcers and recognized the importance of evidence based nursing care for the hospitalized patients with pressure ulcers and was motivated to conduct the present study. This enabled the researcher to carry out

experimental study to assess the effectiveness of aloe vera and olive oil on prevention of pressure ulcers.

a. Statement of the Problem: A comparative study to evaluate the effectiveness of Aloe-Vera gel versus Olive oil in preventing Pressure Ulcer among bedridden patients admitted in a selected hospital, Jammu Kashmir, India.

b. Projected Outcome: Aloe Vera and Olive oil can aid in reducing the incidence of pressure ulcers.

c. Research question: Does application of Aloe-Vera gel more effective than Olive oil in reducing the risk of Pressure Ulcer among bedridden patients admitted in selected hospitals, Jammu Kashmir, India?

d. Objectives

1. To assess the risk for developing pressure ulcer among bed ridden patient in the experimental and control group.
2. To evaluate the effectiveness of Aloe-Vera gel application on prevention of pressure ulcer among bed ridden patient in the experimental group I.
3. To evaluate the effectiveness of Olive Oil application on prevention of pressure ulcer among bed ridden patient in the experimental group II.
4. To compare the effect of Aloe vera gel versus Olive oil application on prevention of pressure ulcer among bed ridden patients.
5. To find out the association between the risk level of pressure ulcer among bed ridden patients and selected socio demographic variables in experimental and control group.
6. To find out the association between the risk levels of pressure ulcer among bed ridden patients and selected clinical variables in experimental and control group.

e. Research Hypothesis

1. **H1**: There will be a significant difference of Pressure Ulcer risk before and after Aloevera application among bedridden patients in the (experimental group I).

2. **H2**: There will be a significant difference of Pressure Ulcer risk before and after Olive oil application among bedridden patients in the (experimental group II).
3. **H3**: There will be a significant difference between the effectiveness of Aloevera gel and Olive oil application on prevention of pressure sore among bedridden patients.
4. **H4**: There will be a significant association between the risk level of pressure ulcer and selected socio demographic variables in the experimental, control group.
5. **H5:** There will be a significant association between the risk level of pressure ulcer and selected clinical variables in the experimental, control group.

f. Operational Definitions:

1. **Effectiveness:** In this study, it refers to reduce the incidence rate of pressure ulcer after topical application of Aloevera gel and Olive oil on pressure ulcers among experimental groups along with routine nursing care (2nd hourly position changing, heel elevation with pillow, flow mattresses) and it is assessed by using National Pressure Ulcer Advisory Panel (NPUAP) grading system for pressure ulcer.

2. **Pressure Ulcers:** In this study, it refers to reduction of risk of Pressure ulcer by selected nursing intervention such as position changing 2nd hourly, and heel elevation with pillow along with application of topical Aloe vera gel to experimental group I and olive oil to experimental group II three times a day for ten consecutive days among bedridden patients and it is measured by using National Pressure Ulcer Advisory Panel (NPUAP) grading system for pressure ulcer.

3. **Bedridden Patients:** In this study, it refers to the patients who are unable to change their position independently and who are between moderate to high risk based on Braden Pressure Ulcer risk assessment scale.

4. **Aloevera gel:** Aloe vera is an amazing mixture of more than 200 constituents, including polysaccharides (a complex carbohydrate), enzymes (complex proteins), glycoproteins, amino acids, vitamins and minerals which helps to reduce inflammation, speed the healing of wounds, ameliorate pain, improve vascular flow, and reduce scarring. 30% Aloe-Vera 5-8ml in a hydrophilic emulsion form prepared from natural aloevera plants applies twice daily for 10 days to high risk pressure prone areas. The commercial preparation of GMP certified aloevera manufactured by Ayurveda pharmacy, Desh Bhagat University Punjab to be used.

5. **Olive Oil** : olive oil refers to an natural olive oil prepared by Indus valley Organic products manufacturing company that is readily available and contains 98 percent triglycerides and 0.6 percent free fatty acids, 0.4 percent glycerol, 0.5 percent phosphatides, and 0.5 percent sterols, among other things; apply 5-8 ml of olive oil topically on pressure points for 5 to 10 minutes two times a day for 10 consecutive days.

g. Limitations

- The study will limited to those patients who are admitted in the wards.
- The study will limited to those patients who are between moderate to high risk based on Braden Pressure Ulcer risk assessment scale.

h. Assumptions

- Local application of Aloe vera may fasten the wound healing process.
- Local application of Olive oil may help in preventing the pressure ulcers.

REVIEW OF LITERATURE

The researcher has reviewed the literature relevantly and organized under the following headings:

1. Studies related to pressure ulcers and prevention of pressure ulcers.
2. Studies related to effectiveness of aloe vera in prevention and healing of pressure ulcers.
3. Studies related to effectiveness of olive oil in prevention and healing of pressure ulcers.

1. Studies related to pressure ulcers.

Borojeny AL. (2020), conducted a systematic review and meat-analysis to assess the incidence of pressure ulcers. It was observed that the incidence of pressure ulcer of first, second, third and fourth stages were 45%, 45%, 4% and 4% respectively among the hospitalized patients (orthopaedic ward).[xxvii]

Ebi EW. (2019), carried a cross – sectional study to explore the knowledge of nurses regarding pressure ulcer prevention. It was observed that 91.5% of the study participants had inadequate knowledge regarding pressure ulcer prevention and the shortage of pressure relieving devices, lack of staff and lack of training were the commonest obstacles in pressure ulcer prevention practices.[xxviii]

Courvoisier SD (2018), demonstrated the variation in pressure ulcer prevalence and prevention in nursing homes in a multicentred study. Total 51 institutions were involved in the study and it was found that overall prevalence of pressure ulcer was 5.7% which was significantly associated with Braden risk, number of preventive measure, size of institution and length of hospital stay. [xxix]

Moore Z (2015), conducted a cross sectional survey to assess the prevalence and prevention of pressure ulcers. A total of 180 patients were involved in the study from Norway and Ireland. Among them 48% were male and 49% were females and 3% patients' gender was not recorded. It was reported that the prevalence of pressure ulcer was 54% in the Norwegian region and 50% in the Irish region. 15% patients had risk of pressure ulcer development in Norwegian region and 56% in the Irish region.[xxx]

Gedamu Haileyesus (2014), conducted a cross-sectional study with the aim to assess the prevalence and associated factors of pressure ulcers among hospitalized patients. Among 422 patients it was observed that 71 pressure ulcers were developed and the prevalence rate was 16.8%. It was observed that the prevalence of pressure ulcr was more in male than female and 62% patients had stage I pressure ulcers and 26.8% had stage II pressure ulcers. Most of the common site of development of pressure ulcer was sacral region (70.4%) and 49% patients had increased hospital stay.[xxxi]

Stevenson Rebecca. (2013), conducted a cross sectional observational study to evaluate the prevalence of patients with pressure ulcers in two different community settings. It was reported that the prevalence of pressure ulcers in community setting 1 was 0.77 per 1000 population and in community setting 2 the prevalence rate of pressure ulcer was 0.40 per 1000 population.[xxxii]

Smith BME. (2013), carried a systematic review with the aim to compare the effectiveness and safety of treatment strategies for adults with pressure ulcers. It was observed that healing of

pressure ulcers in adults is improved with the use of air-fluidized beds, protein supplementation, radiant heat dressings, and electrical stimulation.[xxxiii]

Alves P. (2013), conducted a study to compare the incidence and prevalence of pressure ulcers in community settings and care differentiated the indicators of quality of care. It was reported that the rate of prevalence varies in Europe between 3 and 28%, and the locations with the highest incidences services and intensive care medicine.[xxxiv]

2. Studies related to effectiveness of aloe vera in prevention and healing of pressure ulcers.

Rajveer Singh (2020), conducted an experimental study to assess the efficacy of aloe vera dressings in the management of decubitus ulcer among bedridden patients. The findings demonstrated that in experimental group 40% of patients with decubitus ulcer were healed early and 60% were in wound regeneration stage and in control group 100% were in wound regeneration stage. The study concluded that the application of aloe vera dressings promote wound healing in among the patients with wound healing.[23]

Davood Hekmatpou (2019), in a triple blind clinical trial demonstrated the effect of aloe vera gel on prevention of pressure ulcers in 80 orthopaedic patients. Patients were classified into two groups control and experimental. The control group received only routine nursing care and control group received the aloe vera gel along with the routine nursing care. Findings revealed that the mean age of patients in the control group was (42.34 ± 12.19) and in the experimental group was (41.71 ± 11.50) years, respectively. 1 patient with hip pressure ulcers and 2 patients with sacral pressure ulcers were reported in experimental group. In control group 3 patients with hip pressure ulcers and 8 patients with sacral pressure ulcers were reported. It was found that there was significant association between aloe vera gel application and prevention and occurrence of pressure ulcers.[xxxv]

Zanaty MM (2017), carried a quasi experimental study to evaluate the effect of aloe vera on second degree pressure ulcers among 60 critically ill patients. It was observed that there were a highly statistical significant differences between the experimental and control groups regarding

pressure ulcer characteristics in terms of size, depth, edges, wound undermining presence, skin color surrounding wound, granulation tissues presence, and epithelial tissues presence (P < 0.001**) at post intervention assessment. So, the aloe vera cream was an effective non-pharmacological management in early healing of the pressure ulcer wound.[26]

The conceptual framework to adopted for this study is as follows:

Wiedenbach's Helping Art of Clinical Nursing Model.

MODIFIED WIEDENBACH'S THEORY OF HELPING ART CLINICAL NURSING-(1964):

According to Wiedenbach the practice of nursing comprises a wide variety of services each directed towards the attainment of one of its five components. Realities refer to physical, physiologic, emotional and spiritual factors that come into play in a situation involving nursing actions. The five realities identified by Wiedenbach are agent, recipient, goal, means, and frame work.

- **Agent:** The agent is the practicing nurse who has the personal attribute commitment and competence to provide nursing care. In this study agent will be the nurse who provides Aloe Vera Gel and olive oil for the pressure ulcer Subjects.
- **Recipient**: The recipient will be the one who receives the nurse's actions. In this study the recipients will be the bedridden Subjects
- **Goal**: The goal is the nurse's desired outcome. In this study the goal will be to decline the rate of pressure ulcers.
- **Means**: The means are the activities and devices used by the nurse to achieve the goal. In this study Aloe Vera Gel and olive oil will be the means of improving healing of pressure ulcers.
- **Frame work**: It refers to the facilities in which nursing is practiced. In this study the frameworks are the selected wards.

Methodology

A number of principles were therefore considered important in the design of this study to ensure enhanced methodological rigor in addressing the study research questions. The

study aimed to adhere to the following principles:

1. The study needs to be experimental (True/Quazi) in design to evaluate the effectiveness of Aloe-Vera gel versus Olive oil in preventing Pressure Ulcer among bedridden patients

2. Broad eligibility criteria were used in order to obtain a representative sample including bed ridden Patients admitted in the selected Hospital in Jammu Kashmir.

3. Eleven days follow-up was used to ensure sustainability of improvement.

4. A broad assessment using different outcome measures that includes the risk reduction, along with incidence, stages, location and day of occurrence of Pressure Ulcer to evaluate the effectiveness of the aloevera and Olive oil application.

5. Reliable and valid research instruments that are highly valid, more reliable and scientifically appropriate to the study population were used to measure the risk reduction of Pressure Ulcers. As well incidence, stages, location and day of occurrence of Pressure Ulcer were also measured.

Research approach

In view of nature of the problem and to accomplish the objectives of the study, a quantitative, quasi-experimental research approach was adopted for study. Quantitative research is a formal objective, systematic process for obtaining quantifiable information about the world; presented in numeric form, analyzed through the use of statistics; used to describe and to test relationship; and used to examine the cause and effect of relationships. Quazi experimental approach is an intervention study in subjects are not randomly assigned to treatment conditions but, the researcher exercises certain control to enhance the study's internal validity. In this study, study subjects were not randomly assigned, though allocation of cases/samples into experimental and control group were assigned randomly.

Research design

A research design is defined as the overall plan for addressing question, including specifications for enhancing the study's integrity. A pre-test post-test control group design was adopted to accomplish the main purpose of the study i.e. to evaluate the effectiveness of Aloe-Vera gel versus Olive oil in preventing Pressure Ulcer among bedridden patients admitted in a selected hospital, Jammu Kashmir, India (figure A).

Group	Pre test Day 1st O_1	Intervention Day 1st to 10th	Post test Day 11th O_2
Control (C)	O_{1C}	----------***---------	O_{2C}
Experiment Group I (E^I)	O_{1E}^I	Application of Aloevera gel	O_{2E}^I
Experiment Group II (E^{II})	O_{1E}^{II}	Application of Olive Oil	O_{2E}^{II}

Figure A: Pre-test post-test control group design

ResearchVariables

A. **Independent variable**: **Application of Aloevera gel and Olive oil**

- Routine nursing care practices to control and experimental groups which involves:
- 5-8 ml of topical Aloevera gel for experimental group I applied for five to ten minutes twice daily (8.00am and 8.00pm) for 10 days.
- 5-8 ml of topical olive oil for experimental group II applied for five to ten minutes twice daily (8.00am and 8.00pm) for 10 days.
- The gel and oil applied gently without pressure on the pressure areas to bedridden patients for 10 consecutive days along with routine nursing care.

❖ **Dose, Duration and Frequency of Interventions:**

- **1st Intervention Aloevera**: 30% Aloe-Vera 5-8ml in a hydrophilic emulsion form applies twice daily for 10 days to high risk pressure prone areas (back of the ears, the shoulders, the elbows, the lower back and buttocks, the hips, the inner knees, and the heels) and Commercial preparation of aloevera was manufactured by Tymon Health care private limited, Ludhiana, Punjab was used and it was ISO-GMP certified.
- **2nd Intervention Olive Oil:** Indus Valley Bio Organic Extra Virgin Olive oil 5-8 ml applies twice daily for 10 days to high risk pressure prone areas. Olive Massage Oil was obtained by the cold pressing and grinding of natural olives. Indus Valley is an

Ayurvedic cosmetic brand with a range of natural, organic GMP certified skin care products.

B. **Dependent Variable**

- Level of Pressure Ulcer Risk Reduction
- Incidence of Pressure Ulcer along its stages, sites and occurrence of Pressure Ulcer

C. Socio-demographic characteristics: Age in years, gender, body built and habits

D. Clinical Variables: Braden Pressure Ulcer risk level, Level of consciousness, incontinence, mobility, co-morbidity, elevation of head of bed, skin turgor, and treatment modality.

Setting of the study

Jammu and Kashmir (J&K) is a Union Territory (UT) of India, formerly one of the largest princely states of India located in the country's northern part and is bounded to the east by the Indian union territory of Ladakh, to the south by the Indian states of Himachal Pradesh and Punjab, to the southwest by Pakistan, and to the northwest by the Pakistani-administered portion of Kashmir.

The **Jammu division** is a revenue and administrative division within Jammu and Kashmir, a Union territory of India. It consists of the districts of Jammu, Doda, Kathua, Ramban, Reasi, Kishtwar, Poonch, Rajouri, Udhampur and Samba. Most of the land is hilly or mountainous, including the Pirpanjal Range which separates it from the Kashmir Valley and part of the Great Himalayas in the eastern districts of Doda and Kishtwar. Its principal river is the Chenab.

The hilly regions to the south and southwest of the Kashmir Valley formed the **Jammu Province** of the princely state of Jammu and Kashmir. Jammu city is the largest city in Jammu and the winter capital of Jammu and Kashmir. It is also known as "City of Temples" as it has many temples and shrines, with glittering *shikhars* soaring into the sky, which dot the city's

skyline, creating the ambiance of a holy and peaceful city. A majority of Jammu's population practices Hinduism, while Islam and Sikhism enjoy a strong cultural heritage in the region.

Present study was conducted in Jammu Medical College and Hospital situated at Jammu districts of Jammu Kashmir which was selected purposely.

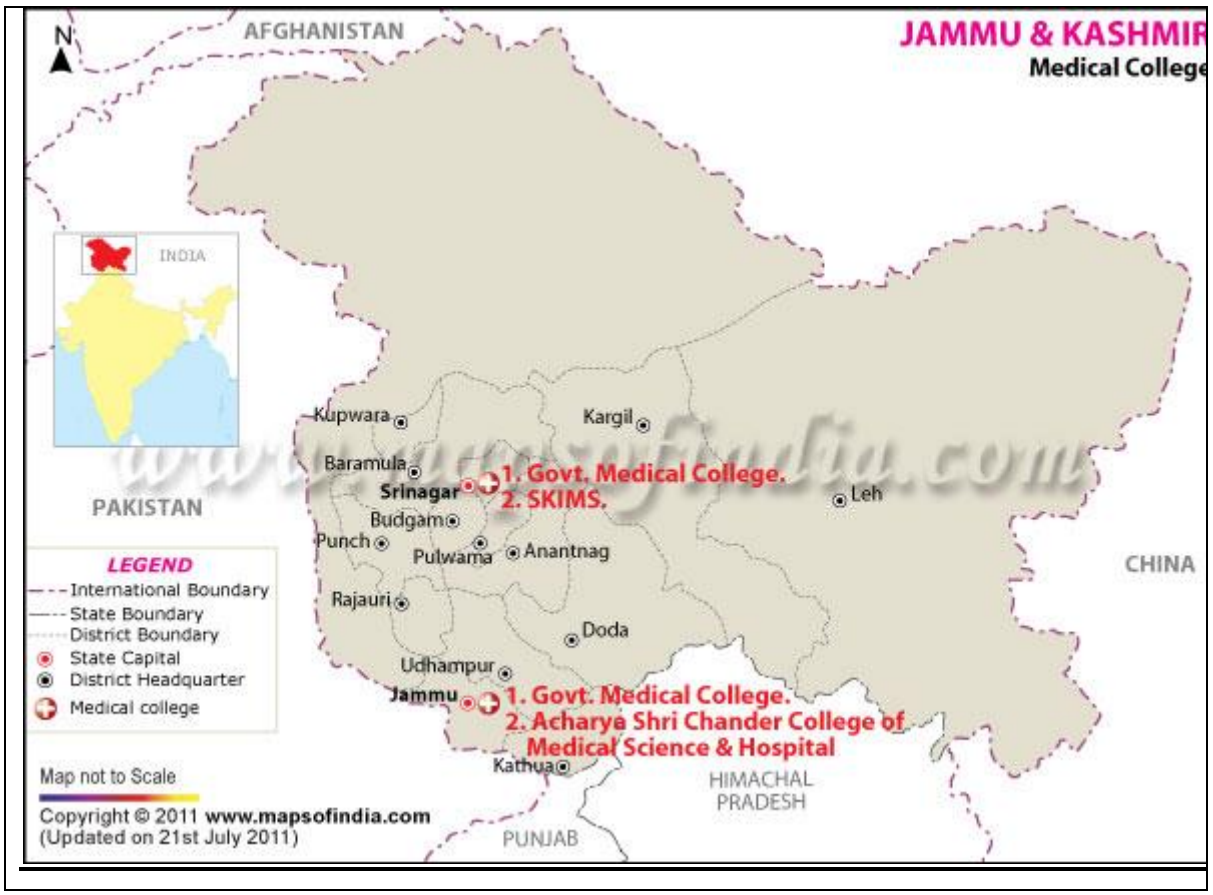
Jammu Government Medical College and Hospital: This institution is located in the heart of Temple City Jammu. Jammu Government Medical College was established in 1972 to serve as referral hospital for Jammu Province. Its aim is to produce knowledgeable, skilled, and competent primary care physicians in compliance with the Medical Council of India (MCI) regulations and to provide health service to the people of Jammu and Kashmir. The institute initially started with 50 medical graduates and soon grew to 180 undergraduates per year (UG) and now has another fifty students. In 1974, GMC Jammu was added to their list as a chest hospital, psychiatric and fever hospital. By the beginning of the second decade, the institute had begun 16 MD / MS postgraduate (PG) and 6 diploma courses. Also, the Institute is ready to start six full-time courses in six super specialties. There are approximately 350 faculty and 1000 support staff in medical education, research, and patient care. In addition, many graduates and post-graduates from this medical college contribute to the advancement of medical research at the national and international levels. The GMC is associated with five teaching hospitals: Jammu Medical College Hospital, CD Hospital, SMGS Hospital, and Psychiatry Hospital & Dental Hospital. This State-of-the-Art Tertiary care Hospital caters to patients across more than 20 different specialities, the total bed strength is 1200, with an average IPD is 900 and as well 160 bed assigned to Orthopaedic care units.

Table 1: Details of Jammu Medical College Hospital

Established	1972
Institution Type	Government
Affiliated University	Jammu University

Post Graduate Courses	20
Super Speciality Courses	4
Total Beds	1200
Average Patients	900-1000
Speciality areas	Emergency, Emergency ICU Neurology, Cancer Chemo, Cardiology, Respiratory ICU, CCU,ICU,ITU, Burn, Medicine, Surgery, Orthopedics etc,
Address	Maheshpura Chowk, Bakshi Nagar, Jammu, Jammu and Kashmir- 180001

Figure 2: The Map of Jammu province showing study setting



Jammu Government Medical College & Hospital located in Jammu district were approached to get permission. This hospital was selected who gave the permission to conduct study in their institution and made bed ridden patients available for study. Researcher successfully got written permission to conduct main study in this hospital.

Population

Population refers to complete set of elements (persons or objects) that possess some common characteristics defined by sampling criteria established by the researcher. The target population is the entire group of people or objects to which the researcher wishes to generalize the study findings. It meets the set of criteria of interest to the researcher. Accessible population is the aggregate of cases that conform to designated set of criteria and who are also available for the research study.

The target population of present study consisted of all the bedridden patients admitted in the orthopedics wards of selected hospital. The accessible population for the study was the bedridden patients who have moderate to high Braden pressure ulcer risk assessment score; admitted in the orthopedics wards of selected hospital who were actually studied by the researcher.

Sampling technique and sample

Sample

The sample is the selected elements (people or objects) chosen for participation in a study. Sampling is the process of selecting a portion of the population to represent the entire population. Sample consisted of bedridden patients of selected hospital, those meeting the inclusion criteria were selected by the researcher for the study. The group included only those having high to moderate Braden pressure ulcer risk assessment score admitted in the orthopedic wards of selected hospital. The eligibility criteria were presented in table.

Inclusion criteria	Exclusion criteria
• **Subjects admitted in the Orthopedics wards of selected hospital.** • **Subjects within the 48 hours of hospitalization in the orthopaedics**	• Subjects who were discharge in between the data collection phase. • Having Mild Braden Pressure ulcer

wards with no pressure ulcers were chosen. • **Having moderate to high risk (9-14) Braden pressure ulcer score (NPUAP).** • **Subjects willing to participate.** • **Subjects insensitivity to topical Aloe Vera gel and Olive oil.** • **Subjects age over 18.**	risks. • Reluctance to continue cooperation.

Sample size

Software program Open EPI Info Version 3 was used to compute the required sample size(N) for conducted significance difference between groups. The minimal sample size was determined to be 210 sample size based on the same study's calculations of 80% testability/power under the standard required power (1-β) of 0.8 and Type I error (□) of 0.05, 95% degree of confidence, 40% incidence of bed sores, 20% exposure to result (occurrence of pressure ulcers), and 40% power of unexposed to outcome (incidence of pressure ulcer). The total number of samples needed, as calculated using open Epi software, is 150–170.

Keeping in mind for the possibility of subject's attrition during the 11 days follow up of the study, a dropout rate of 30% was computed approached 232 patients at the beginning but finally, 210 patients completed the study. Thus, sample size comprised of 210 patients 70 each in 1st experimental group, 2nd experimental group and 3rd control group (1/1/1) allocation. As a result, the total sample size was 210, which was divided equally among the experimental group I (70), experimental group II (70), and control group (70) groups.

$$n = N_x \frac{\frac{z^2 * p * (1-p)}{e^2}}{N - 1 + \frac{z^2 * p * (1-p)}{e^2}}$$

Sampling technique:

It was a two steps process (figure):

1. Firstly, researcher purposely selected the bed ridden patients.
2. Bedridden patients who were admitted in the orthopaedic ward within 48 hours were approached and assessed/screened for Braden pressure ulcer risk score purposely.
3. On the basis of moderate to high Braden pressure ulcer risks and expected availability of more than 11 days as well. These bedridden patients were listed in the sampling frame for the main study. The simple randomization plan was created by lottery method and the subjects were randomly assigned to either both experimental or control groups. It helped to avoid the possibility of contamination of intervention between experimental and control group subjects.
4. Then, the sampling frame was created after every 11^{th} day until the required number of samples involved, thus in every phase of sampling frame only 9 to 10 subjects were involved till the required number of subjects has been reached.

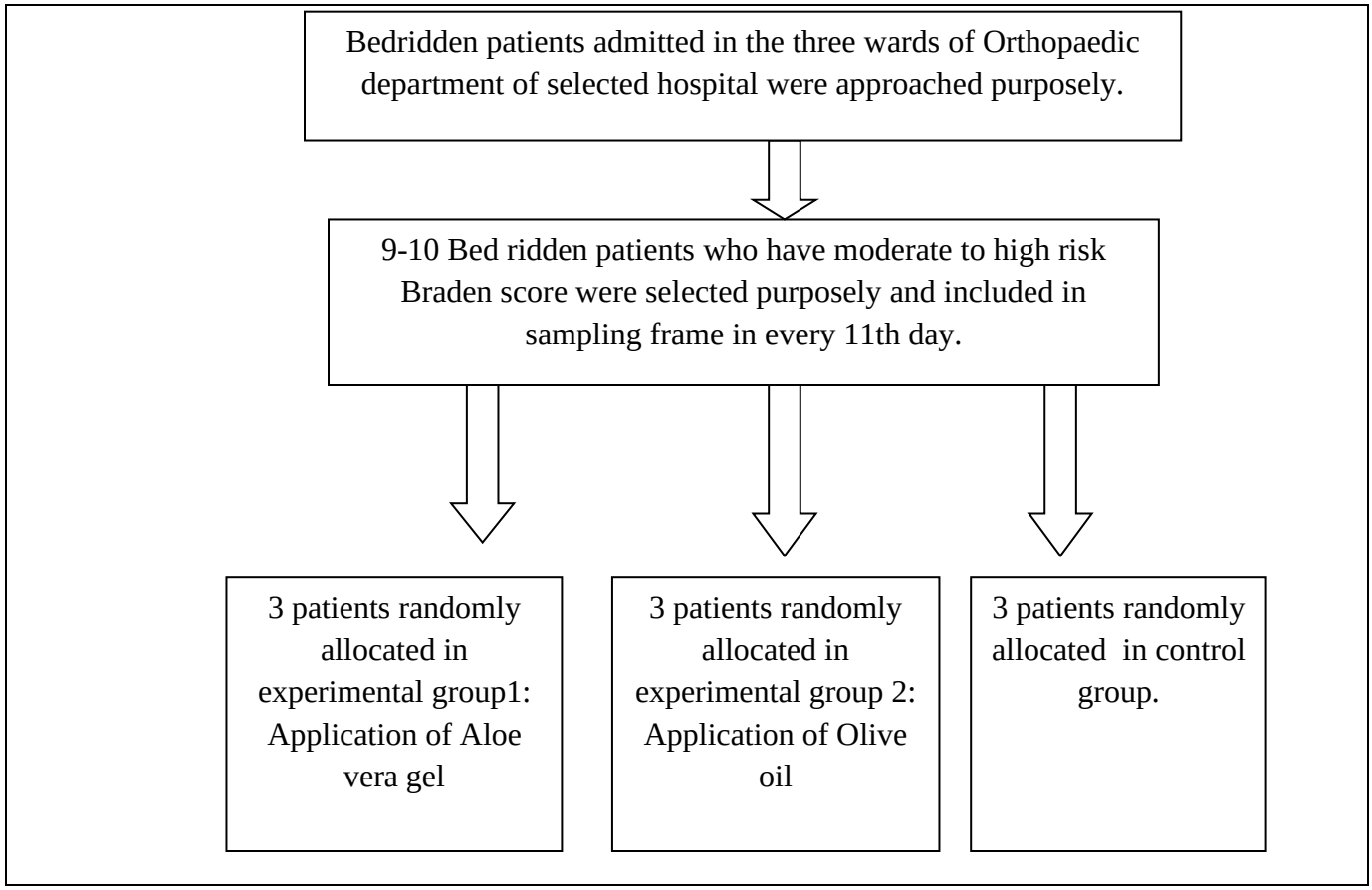


Figure B: Sampling plan for the study for single phase

Data collection tools and techniques

Development/selection of the tools

Reliable, valid and standardized research instruments that were scientifically appropriate to the study population were used to measure the socio-demographic characteristics, clinical variables, risk reduction level, incidence, stages& sites, day of occurrence among bed ridden patients admitted in orthopedics wards of selected hospital (Appendix).

Tool no.1-Socio-demographic and clinical variables data sheet

Socio-demographic and clinical variables data sheet is used for recording of socio demographic and clinical details of the bedridden patients and to establish the representative nature of sample at baseline. It was developed by researcher in expert guidance of guide. Administration time is approximately 4-5 minutes. This tool had two parts.

Part A: **Socio-demographic data sheet:** It has total four items related to socio-demographic Information of the bedridden patients which are age, gender, body built and habits.

Part B: **Clinical variables:** It has total eight items related to **clinical variables** of the bedridden patients which are Braden pressure ulcer risk level, Level of consciousness, incontinence, mobility, co-morbidity, elevation of head of bed, skin turgor, and treatment modality.

Tool no: 2- Barbara Braden and Nancy Berg storm Pressure Ulcer Risk Assessment Scale.

Part A: Barbara Braden and Nancy Berg storm Pressure Ulcer Risk Assessment Scale

In this study Barbara Braden and Nancy Berg storm Pressure Ulcer Risk Assessment Scale was used (before and after the intervention) to assess the pressure ulcer risks among bed ridden patients. This is a clinical tool use to assess risk of a patient/client developing a pressure ulcer. The primary aim of this tool is to identify patients/clients who are at risk, as well as determining the degree of risk of developing a pressure ulcer. The Braden Scale is a scale made up of six subscales, which measure elements of risk which contribute to either higher intensity or duration of pressure, or lower tissue tolerance for pressure. These are: sensory perception, moisture, activity, mobility, friction, and shear. Each item is scored between 1 and 4, with each score accompanied by a descriptor. The lower the score, the greater the risk.

Scoring criteria

This tool was used during the assessment phase of subjects in pre test (1^{st} day) and post test (11^{th} day) to assess the risk reduction level of pressure ulcer.

The total score runs from 6 to 23, and it is calculated using a 3 or 4 point scale. The tool identifies four ‘at risk' categories,

1. a score of < 9 indicates 'severe risk'
2. a score of 10-12 indicates 'high risk',
3. a score of 13-14 indicates moderate risk
4. a score of 15-18 indicates 'mild risk'
5. a score of 18+ indicates 'low risk'

The total score is obtained by adding numerical responses to each subscales. Scoring of subscales is done as mentioned below. These subscales are:

1. Sensory perception (4-point scale)
2. Moisture (4-point scale)
3. Activity (4-point scale)
4. Mobility (4-point scale)
5. Nutrition (4-point scale)
6. Friction and shear (3-point scale)

Accordingly, total score of subscales are 6 to 23. Each item is scored between 1 and 4, with each score accompanied by a descriptor.

This scale used to ensure risk assessment fully documented along with full skin inspection, Implement preventative measures according to′ identified risk and regularly evaluate effectiveness of interventions′.

Tool no.3: Modified European Pressure Ulcer Advisory Panel (EPUAP) grading/classification system for pressure ulcer .

Pressure ulcer classification system is a valuable tool to provide a common description of ulcer severity. As well, risk assessment remains a key component of Pressure Ulcer prevention **thus the** European Pressure Ulcer Advisory Panel grading system for pressure ulcer assessment was used in this study also. The European Pressure Ulcer Advisory Panel grading system for pressure ulcer was created in London in December 1996 in the efforts to prevent and treat pressure ulcers. The first edition of the guideline on prevention and treatment of pressure ulcers was developed as four year collaboration between the National Pressure Ulcer Advisory Panel (NPUAP) and the European Pressure Ulcer Advisory Panel (EPUAP). In this second edition of the guideline, the Pan Pacific Pressure Injury Alliance (PPPIA) has joined the NPUAP and EPUAP. The goal of this international collaboration was to develop evidence-based recommendations for the prevention and treatment of pressure ulcers that could be used by health professionals throughout the world.

The EPUAP/NPUAP/PPPIA was recommended the pressure ulcer grading/classification system in its 3rd edition published in 2019. The validated grading system adopted for this study to measure the incidence, stages, and location of pressure ulcer among selected subjects which was again updated in 2019.. In the present study The EPUAP was adjusted/modified to assign scores only to its prescribed pressure ulcer severity grades. Accordingly, the international EPUAP/NPUAP pressure ulcer classification system recommended the following four grades/category/stages of pressure ulcers.

Grade I: Nonblanchable Erythema

Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may different from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue.

Grade II: Partial Thickness Skin Loss

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serumfilled blister. Presents as a shiny or dry shallow ulcer without slough or bruising.

Grade III: Full Thickness Skin Loss

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast,areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

Grade IV: Full Thickness Tissue Loss

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow.

Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.

Unstageable: Depth Unknown

Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore Category/Stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as 'the body's natural (biological) cover' and should not be removed.

After merely giving scores to the recommended EPUAP pressure ulcer severity grades by the researcher; the modified EPUAP pressure ulcer classification system was employed in this study in the following way. If the subject displays grade I pressure ulcer symptoms, a score ranging from 1 to 15 was given based on the severity of the symptoms. Grade II pressure ulcer symptoms result in a score between 16 to 20, whereas grade III symptoms result in a score more than 20.

Grade I 1 to 15	Warmth, Intact skin with non-blanchable redness, purplish/bluish colour, Edema (non-pitting swelling), taut and shiny skin.
Grade II 16-20	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum - filled or sero-sanginous filled blister. The sore expands into deeper layers of the skin
Grade III More than 20	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are not exposed. Slough may be present but does not obscure the depth of tissue loss. May also present as an intact or open/ruptured serum - filled or sero-sanginous filled blister. The sore expands into deeper layers of the skin

Modified EPUAP Grade- I & II Pressure Ulcer –Scoring

S.No	Description	Score
1.	Warmth & Itching	1
2.	Intact skin with non-blanchable redness	2
3.	Purplish/bluish discolouration of the skin	3
4.	Edema	4
5.	Taut and shiny skin	5
Total score Grade 1 PU		**15**
6.	Partial thickness loss of dermis Grade II	**5**
7.	The sore expands into deeper layers of the skin: Grade II	**5**
Modified Grade-II Decubitus Ulcer –Scoring **15+ (16-20) reflects Loss of dermis as an open ulcer** **20+ (More than 20) ulcer expanding into deepest layers.**		

The sum of a specific item scores was used to determine the final score. The severity of each respondent's scores on the metrics was assessed.

Pressure Ulcer Grade's Risk Level (Modified EPUAP)	Score
Mild risk	1-5
Moderate risk	6-10
High risk ((occurrence of grade I PU)	11-15
Severe risk (occurrence of grade II PU)	16-20

Psychometrics

Braden scale was introduced by the International Pressure Wound Association. The internal consistency of the questionnaire using Cronbach's alpha was reported 0.72. It has acceptably high validation and reliability scores (high internal consistency and stability). The validity of Braden scale was confirmed in national and international studies.

Content validity of all tools was established with panel of ten experts from department of medicine and surgery as well medical surgical nursing departments and language experts too. Panel members were asked to rate each tool for their appropriateness, adequacy, relevance and use among patients. Content validity index was calculated for relevance of items for tool no. 1 and it was 0.9. Necessary suggested modification was done as per discussion with guide. On the whole, the experts opined that tools were comprehensive, systematic and structured. The validity of the socio-demographic and clinical information questionnaires was assessed based on the content validity method.

Reliability

The reliability of a measuring instrument is a major criterion for assessing its quality and adequacy. Reliability is the consistency with which it measures the target attribute. The reliability of the tool will be done by test retest method. Thus, all the tools had high internal consistency. All data collection tools are summarized in table.

S. No.	Structured and Validated Tools
1.	Braden Pressure Ulcer Risk Assessment Scale
2.	Modified EPUAP Pressure Ulcer Classification System

Tool translation

All the research instruments were translated from English to Hindi by language experts. In order to ensure the accuracy of the research instrument, the strategy of back translation was used. An independent bilingual expert then translated the instruments back to English to ensure the meaning of the original tool.

Interventions' procedure

Application of Aloe Vera gel and Olive oil and routine nursing care.)

A. Preparation of Intervention 1 (Aloevera gel)

On the basis of Aloe vera gel's mechanism and botanical properties as background, researcher did in-depth review of literature to understand the role of Aloevera gel in the pressure ulcers prevention and healing. The slightly sticky gel inside each leaf soothes the skin and, according to the National Institutes of Health, studies have shown aloe vera can help promote healing of the skin. Transparent gel from the pulp of the fresh leaves of aloe vera has been used topically for thousands of years to treat wounds, burns, and numerous other dermatologic conditions. The aloe vera gel has immune modulatory properties that may improve wound healing and skin inflammation. The Tymon aloe vera ayurvedic gel was used for study purpose.

Commercial preparation used for the study: Tymon aloe vera gel was an ayurvedic preparation by Tymon health care pvt. Ltd. (Ludhiana, Punjab). It has essential growth promoting substance & principally contains Aloevera which parts nourishment to the skin and it was ISO certified.

Dose: 66 % Aloevera in a hydrophilic emulsion form applied twice a day in an amount of 5-8ml for 5-10 minutes each time gently without pressure for 10 days daily to pressure prone areas.

B. Preparation of Intervention II (Olive Oil):

Olive oil contains the phenolic compounds which have antimicrobial, anti-inflammatory, and antioxidant properties, causing tissue coverage and thus accelerating wound healing. After extensive literature serach, researcher understands that the topical use of olive oil in the prevention of PUs is as effective as HOFA solutions. The virgin Olive oil was also used for stduy purpose.

Commercial preparation used for the study: In this study, Indus Valley bio organic extra virgin olive oil refers to the oil prepared from olives, which is readily available product and it composed of 98% triglycerides and 0.6% free fatty acids, 0.4 % glycerol, 0.5 % phosphatides and 0.5 % sterols etc; application of 5-8 ml while providing effleurage, vibration techniques of back massage for 5-10 minutes twice a day.

In the olive oil group, 100% pure olive oil was made by Indus valley Company.

Dose: The virgin form (100% pure olive oil) of olive oil applied twice a day in an amount of 5-8ml for 5-10 minutes each time gently without pressure for 10 days daily to pressure prone areas. The preparation was offered in a 100ml packaged jar of olive oil. Each subject of experimental group II received two to three jar of Olive oil.

C. Routine nursing care to Control and Experimental groups:

Furthermore in the intervention and control groups, all the study subjects including control received routine nursing care including observing the patient's skin hygiene, proper nutrition, change position every 2hourly, pressure relief mattress, and prevention of skin damage and changing linen. The researcher implemented the following routine nursing care preventive practices recommended by NPUAP/EPUAP/PPPIA to prevent pressure ulcers.

- Keep the skin clean and dry
- Use a pH balanced skin cleanser.
- Do not massage or vigorously rub skin that is at risk of pressure ulcers.
- Cleanse the skin promptly following episodes of incontinence.
- Protect the skin from exposure to excessive moisture with a barrier product in order to reduce the risk of pressure damage.
- Do not use dimethyl sulfoxide (DMSO) cream for the prevention of pressure ulcers.
- Do not apply heating devices (e.g., hot water bottles, heating pads, built-in bed warmers) directly onskin surfaces or pressure ulcers.
- Consider using silk-like fabrics rather than cotton or cotton-blend fabrics to reduce shear and friction.
- Provide adequate protein for positive nitrogen balance for adults assessed to be at risk of a pressure ulcer.
- Provide and encourage adequate daily fluid intake for hydration for an individual assessed to be at risk of or with a pressure ulcer.
- Avoid subjecting the skin to pressure and shear forces.
- Use manual handling aids to reduce friction and shear. Lift — don’t drag — the individual while repositioning.
- Avoid positioning the individual directly onto medical devices, such as tubes, drainage systems or other foreign objects.
- Do not leave the individual on a bedpan longer than necessary.
- Use the 30° tilted side-lying position (alternately, right side, back, left side) or the prone position. Avoid lying postures that increase pressure, such as the 90° side-lying position, or the semi-recumbent position.
- Limit head-of-bed elevation to 30° for an individual on bed rest unless contraindicated by medical condition or feeding and digestive considerations.

- Do not use ring or donut-shaped devices. The following 'devices' should not be used to elevate heels: synthetic sheepskin pads; cutout, ring, or donut-type devices; intravenous fluid bags; and water-filled gloves.
- Develop a schedule for progressive sitting according to the individual's tolerance and pressure ulcer response.
- Increase activity as rapidly as tolerated.
- Ensure that the heels are free of the surface of the bed.
- The knee should be in slight (5° to 10°) flexion.
- Use a foam cushion under the full length of the calves to elevate heels.
- Remove the heel suspension device periodically to assess skin integrity.
- Continue to reposition individuals placed on a pressure redistribution support surface.

Validity& Reliability

Both the interventions were ISSO certified.

Ethical considerations

The researcher focused to several important ethical issues regarding obligations and responsibilities in the recruitment of participants and data collection. Prior to administration of tools and intervention, participants were given information verbally and in writing about the nature of the study and informed of their right not to participate, to withdraw at any time without explanation or penalty as they wished. Participants were not under any obligation to give consent for participating in this study. Taking part in this study was entirely voluntary.

Participant information sheet of the study was readout and handed over to the subject with explanation of the purpose. All the questions and queries were discussed and sort out before actual data collection. An informed written consent form was signed by the subject before data collection. All the subjects were ensured that confidentiality and anonymity was maintained throughout the study. Opportunities were provided for the participants to ask questions at any stage.

The data collected is reported in general terms and does not involve any identifying data such as names and address. All data was kept confidential and securely held for the required time period. Data was entered into computerized database and the identity of participants was protected through the use of key code.

Permission was obtained from institutional ethical committee to carry out the study. Written permission was also obtained from Medicine and Surgery Departments, and Principal of the respective hospital before data collection.

Data collection procedure

Permission to conduct study was taken from Principal, Govt. Medical College & Hospital, Jammu; and HoD of Medicine and Surgery departments of GMC, Jammu. Few preliminary visits in each hospital were made in which researcher established rapport with nursing Matron, Ward Incharges, Staff nurses and significant hospital authorities who helped in availability of setting as per need. Nursing matron/ significant authorities were also ensured by researcher that study objectives were not obscure their routine ward duties. The recruitment of samples was conducted in a phase of 11 days. The first day and then on every 11^{th} day, the 9-10 samples were selected for a period of 11 days. (Figure 3)

Firstly, Patients were randomly assigned into two intervention and one control group based on the sampling method. Among study subject groups, patients, those fulfilling the eligibility criteria were explained the purpose of the study. Informed written consent was obtained. The pre- test data was collected by using Braden pressure ulcer risk assessment scale and modified EPUAP scale on day one. It was followed by implementation/application of topical pure aloevera gel on the areas of hip, sacrum and heel were applied topically to experimental group I and virgin olive oil on the areas of hip, sacrum and heel were applied topically to experimental group II twice a day (hours of 9 and 21) along with routine nursing care for 10 consecutive days by the researcher. In each group the routine daily cares to prevent bed sores were performed by researcher. At the end, post-test data were collected on 11^{th} day and a thank was given to the subjects. Initially, 156 subjects were registered for the study in both experimental groups and 76 in control group. But, 210 subjects successfully completed the post-test among all three groups. Approximate time taken was 06-10 minutes for each subject each time to fill all the data collection tools. Subjects of control group were provided with only routine nursing care.

Attrition details

Over seven month's duration, a total of 232 patients meeting the inclusion criteria were approached to participate in the study. Of these, 04 patients refused to participate in the study at very beginning stage. The total number of patients who completed initial assessment and registered were 228. At the end of study, 210 subjects were regular, the remaining 18 (8%) had discontinued due to specific resaons. The dropout rate at the end of this study was 8-11% for intervention group and 6% for control group.

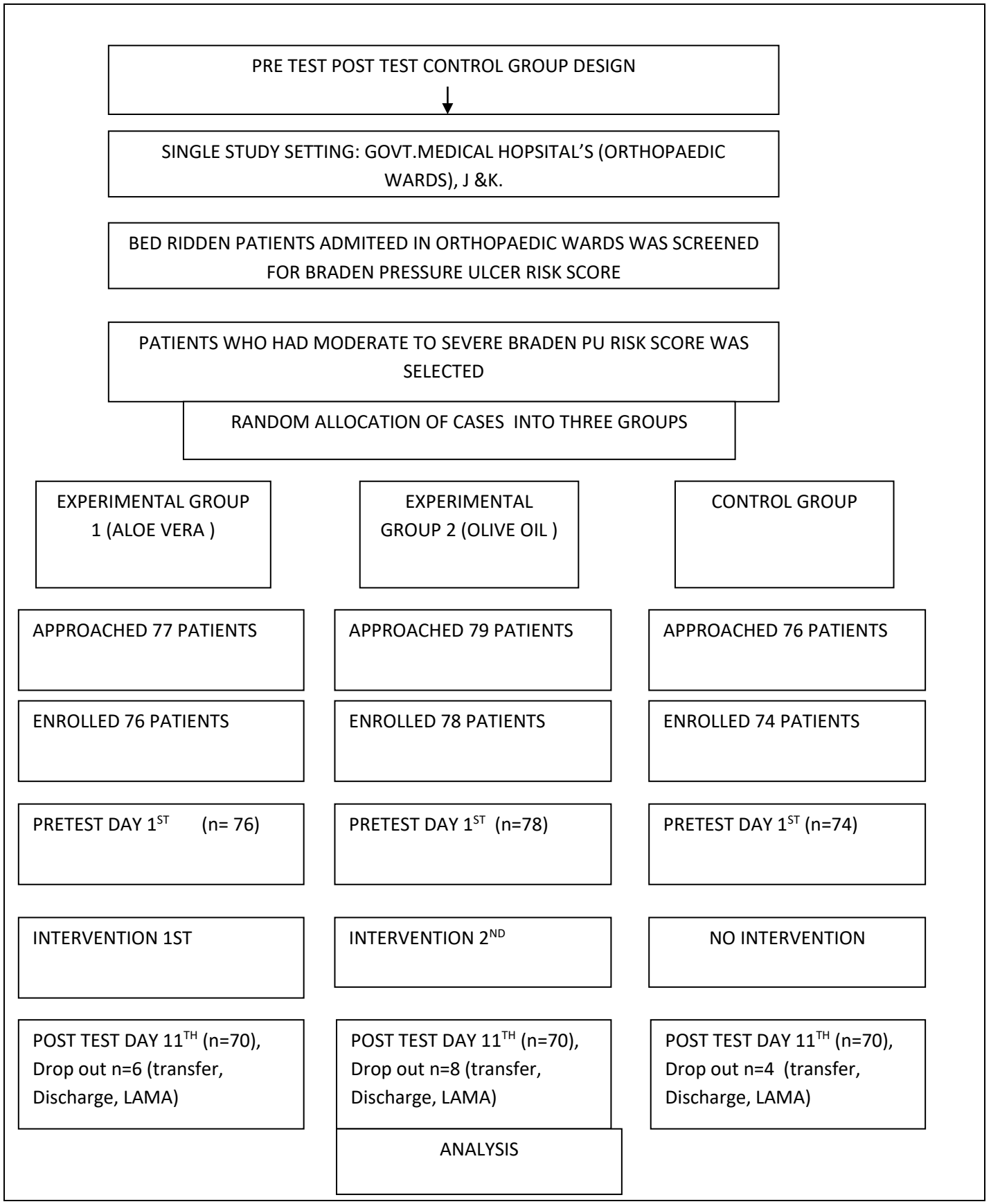
Plan for data analysis

The data was analyzed by Statistical Package for Social Sciences (SPSS) version . The $p<0.05$ level was established as a criterion of statistical significance for all the statistical procedures performed. Collected data was reviewed for completeness and consistency within single data forms and along data forms. Master data sheet along with its coding was prepared. The accuracy of data coding was assured by comparing the computerized data with the original data for a random sample (20%) of the database.

Appropriate descriptive and inferential statistics were employed to analyze data as per objectives and hypothesis of the study. Frequency, range and percentage distribution of sample characteristics was computed. Mean (SD) of pre-test and post-test score of the study subjects was calculated in all groups. Independent't-test' was used to compare the outcome variables between experimental and control group at baseline. Similarly paired 't-test' was employed to compare the baseline and post-test two score of outcome variables in experimental and control group. Tables, figures and diagram (bar, pie, and scatter) were used to depict various data.

Duration of data collection

The data was collected from June 2022 to February 2023.


PRE TEST POST TEST CONTROL GROUP DESIGN
SINGLE STUDY SETTING: GOVT.MEDICAL HOPSITAL'S (ORTHOPAEDIC WARDS), J &K.
BED RIDDEN PATIENTS ADMITEED IN ORTHOPAEDIC WARDS WAS SCREENED FOR BRADEN PRESSURE ULCER RISK SCORE
PATIENTS WHO HAD MODERATE TO SEVERE BRADEN PU RISK SCORE WAS SELECTED
RANDOM ALLOCATION OF CASES INTO THREE GROUPS
EXPERIMENTAL GROUP 1 (ALOE VERA)
EXPERIMENTAL GROUP 2 (OLIVE OIL)
CONTROL GROUP
APPROACHED 77 PATIENTS
APPROACHED 79 PATIENTS
APPROACHED 76 PATIENTS
ENROLLED 76 PATIENTS
ENROLLED 78 PATIENTS
ENROLLED 74 PATIENTS
PRETEST DAY 1ST (n= 76)
PRETEST DAY 1ST (n=78)
PRETEST DAY 1ST (n=74)
INTERVENTION 1ST
INTERVENTION 2ND
NO INTERVENTION
POST TEST DAY 11TH (n=70), Drop out n=6 (transfer, Discharge, LAMA)
POST TEST DAY 11TH (n=70), Drop out n=8 (transfer, Discharge, LAMA)
POST TEST DAY 11TH (n=70), Drop out n=4 (transfer, Discharge, LAMA)
ANALYSIS

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Bushra Karim , Dara John Bhaskar, Chandan Agali, Devanand Gupta, Rajendra Kumar Gupta, Ankita Jain, Alpana Kanwar