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A STUDY OF FACTORS INFLUENCING THE PHARMACOTHERAPY OF DIABETIC FOOT ULCER

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ABSTRACT

Objective of study: The aim of study was to understanding the treatment strategies and factors influencing of diabetic foot ulcers, in patients presenting with diabetic foot at Malabar area in Kerala (hospital and home care units). **Methods:** This prospective analytic study was conducted from June 2013 – Jan 2014 at Govt Hospital and Home care unit in Malabar, Kerala (total population 50). Diabetic patients who presented with foot ulcers were enrolled in this study. Demographics of patients along with ulcer size, age, and site, patient history, past medication, socio economical status, diet controlling, physical activities, patient education and wound management with healing rate were recorded. Wounds were managed with daily dressings, nursing care and debridement of necrotic tissue along with appropriate antibiotic ointments and their outcome are monitored. **Results and discussion:** Out of 50 patients' majority of male population having DFU in the age range of 61-70 years. Out of 28% of good QoL patients only 14.3% of subjects having faster wound healing rate. In 74% of total male population only 16% of them having faster healing rate and females are in good caring in DFU (31%). 42% of subjects were not following physical activities so that 57.2% of them having D grade wounds. out of total population 26% subjects were used metrogyl powder and NS, it showing good healing rate, 76% A grade wounds and no D grade wounds in this method. 54% patients following diet controlling (40.7% A grade wound). 46% of subjects are diabetic educated. 68% of subjects from Govt Hospital in that no A grade wound but 32% of subjects from Home care unit so that 56.25% of A grade wounds are there. **Conclusion:** The result of this study has highlighted the gaps in their knowledge and practice and underscores the urgent need for a

patient friendly educational intervention coupled with regular physician reinforcement to reduce the risk of diabetic foot ulcer and amputations.

KEYWORDS: Diabetic foot ulcer, Quality of life, debridement, off-loading, neuropathy.

INTRODUCTION

Foot ulceration in diabetics cause serious disability and considerable strain over the scarce resources of the patients and the community. Foot ulceration affects around 15% of patients with diabetes[1,2], with a risk of amputation being 15-40 times higher than in non-diabetics3 In U.S.A alone each year it accounts for 30,000 lower extremity amputations, around 20% of all hospital admissions of diabetics and costs more than 200 million dollars per year.[3] The risk of re-amputation and amputation of the other leg is around 40% in five years1. The five year mortality rate in patients with diabetes after amputation is around 70%.[4] However, in recent decades our knowledge on diabetic foot ulcers has clearly increased, with a rise in the number of scientific publications and the production of guidelines on prevention and management.[5,6,7] In this review we describe the epidemiology, costs, pathogenesis, and in particular current treatment modalities for diabetic foot ulcers.

Objectives

- To understand the influences of Demographic variable on patients having Diabetic Foot Ulcer.
- To assess the impact of Patient education on disease, therapy, diet and lifestyle modification in patient having Diabetic Foot Ulcer (DFU).
- To observe the different therapeutic strategies in patients having Diabetic Foot Ulcer.
- To compare the different wound care managements and their outcome of patients under the treatment of Hospital and Home care teams.

METHODOLOGY

A prospective and comparative study was carried out and patients were randomly selected from general ward and Outpatient department in Govt Hospital and Home care unit, Malabar, Kerala, having Diabetic Foot Infection. It included consecutive 50 patients with diabetic foot disease presenting from June 2013 – Dec 2013. All patients presenting during the study period were included.

Inclusion criteria

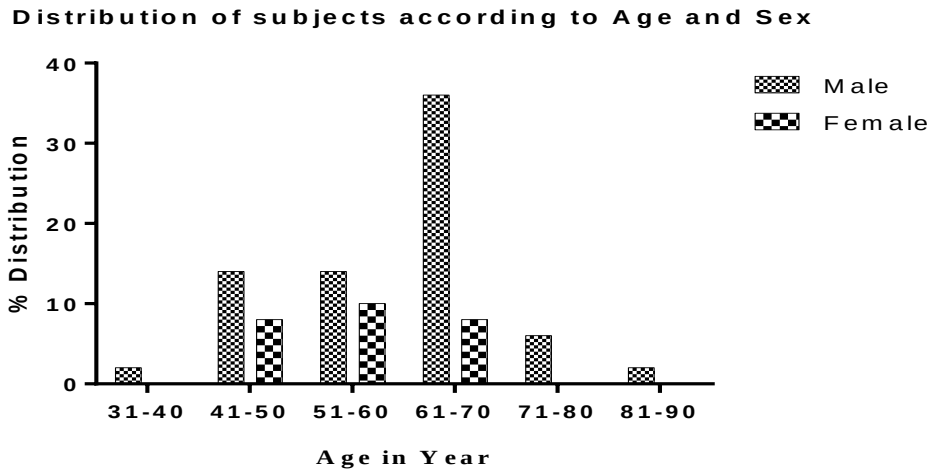
- Patients with Diabetes mellitus presenting with lesions of foot.
- Patients those amputated for diabetic foot.
- Patients aged more than 20 years with diabetic foot ulcer
- Ulcers of Wagener's Grade II – IV

Exclusion criteria

- Patients with chronic foot ulcers due to cause other than DM such as traumatic, arterial, venous and. tropic ulcer.
- Gangrene due to arterial occlusion and embolic phenomenon.
- Abration, Decubitus, Blister, cellulites, abscess and Venous stasis ulcer.
- Patients receiving corticosteroids, immunosuppressive agents, radiation or chemotherapy are also excluded. X-ray showing osteomyelitis.

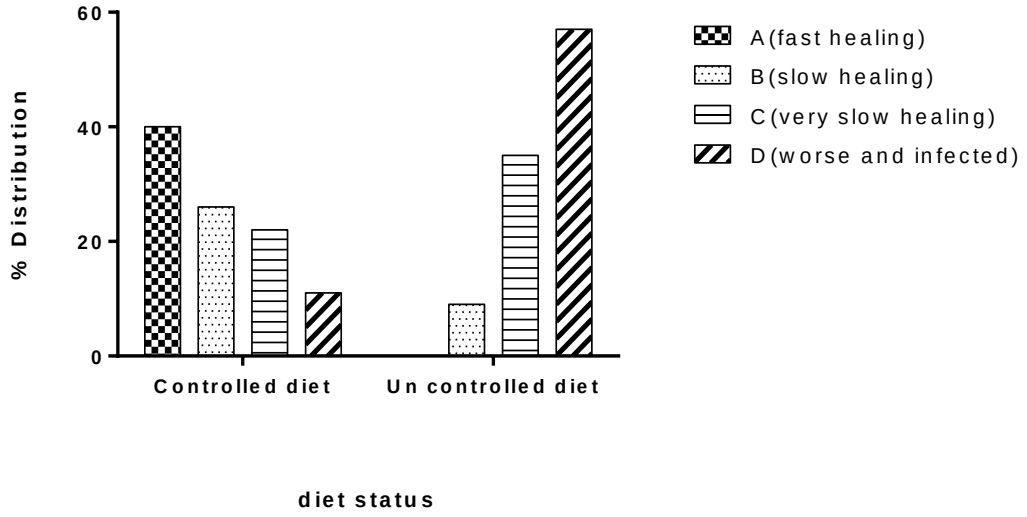
RESULTS

The data revealed that diabetic foot diseases affected males somewhat more frequently (74%) as compared to females (26%). In the present study, It is observed that, out of 50 sample, majority of samples 22 (44%) were in age group of 61-70 years shown in figure-I.



It is observed here that in the present study, out of 50 population, 27% of subjects are following controlled diet and 23% are not following diet controlling. Among the population of controlled diet, 41% of peoples having faster wound healing rate (A (faster healing), only 11% having worse and infected wounds. Among the population of Un controlled diet groups,

none had faster healing wounds (A grade), but 56.5% of these subjects having D grade (worse and infected) wounds.



Distribution of Respondent According to Diet controlling and healing rate

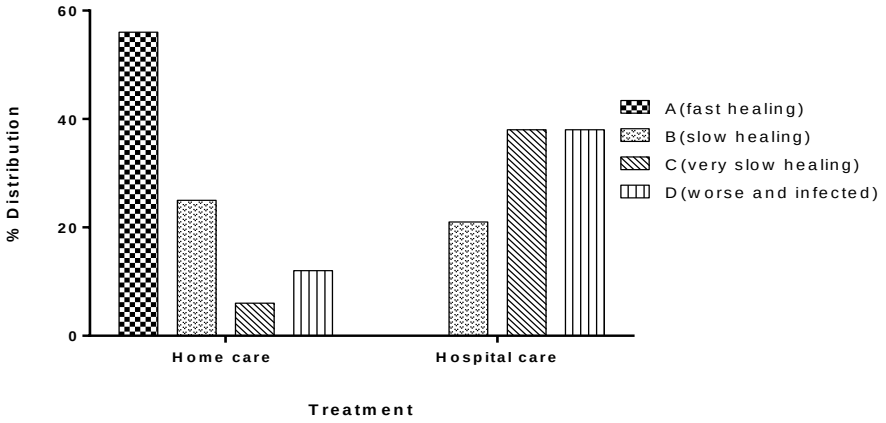
It is noticed in the present study that out of 50 population majority (30%) are using Betadine ointment, 26% of peoples using Metronidazole tablet powder and 18% are using Neosporin powder. only 6% are using Mupricon ointment and Soframycine ointment. Only 2% of subjects using Dimethicon cream, Gentamycine ointment, Sulfadiazine ointment, Clotrimazole ointment, Glycerine MgSO4 paste and Insulin irrigation.

Frequency and Distribution of Respondent by use topical wound care products

Products used	Number	Percentage
Neosporin	9	18
Mupricon ointment	3	6
Metronidazole tablet powder	13	26
Dimethicon cream	1	2
Gentamycine ointment	1	2
Betadine ointment	15	30
Sulfadiazine ointment	1	2
Clotrimazole ointment	1	2
Butenafine ointment	1	2
Soframycine ointment	3	6
Glycerine MgSO4 paste	1	2
Insulin irrigation	1	2

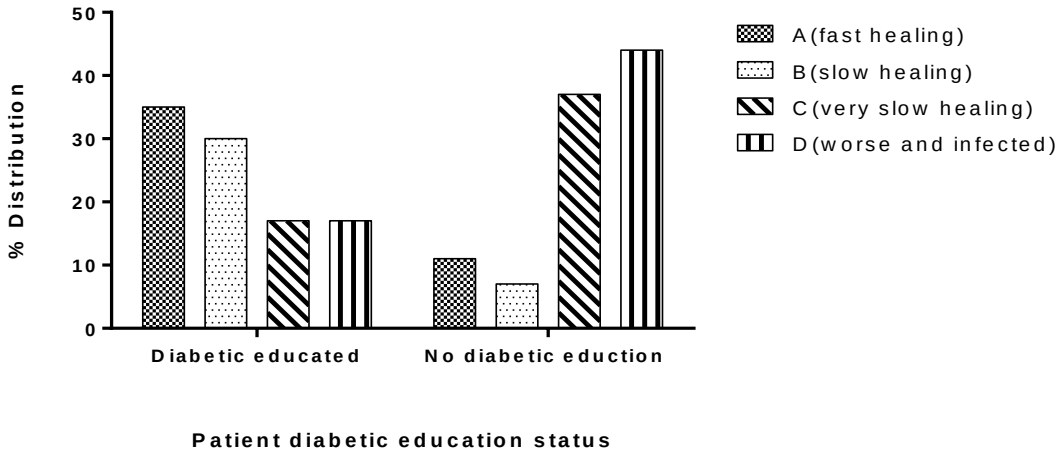
Further it is also observed that out of 50 total populations, 32% subjects are from Home care treatments and 68% of the subjects from Hospital care (In patient department). Amoung

population of Home care units, 156.25% of subjects having faster wound healing rate (A grade wound), and only 12.5% having worse and infected wound(D grade). Among the population of Hospital care, 38.24% subjects having worse (D grade) wound, none had (A Grade) faster healing wound.



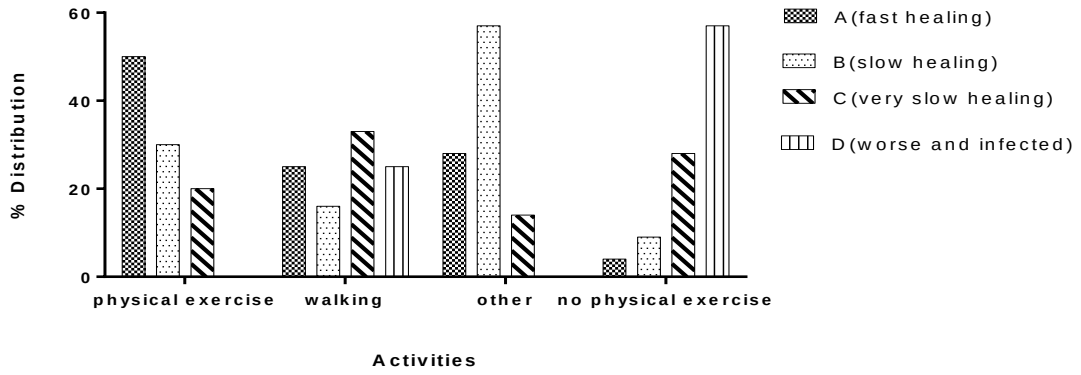
Distribution of subjects according to their treatment category and wound Healing rate

It is observed in the present studies that out of total (50) population, majority of subjects (54%) are not diabetic educated; Only 46% subjects are diabetic educated. Among population of not educated subjects, 11.1% having faster healing wound (A grade) and 44.4% of these subjects having worse and infected wound (D grade). Among the population of Diabetic educated subjects, 34.8% subjects having Faster healing rate (A grade wounds), only 17.4% of subjects having worse and infected (D grade) wound.



Distribution of subjects according to their Diabetic education and wound healing rate

The result observed that out of total population, 10% of subjects are doing Physical exercise, 12% are walking, 7% are doing other activities and 21% are not doing any physical activities. Among the population are doing physical activities, 50% of subjects having faster wound healing rate, the infected wounds was not seen. Among the population of walking, 25% are having worse wounds. Among the population of not doing physical exercise, only 4.7% of subjects having Fast healing wounds and 57.2% of them having worse and infected wounds. Among the population of subjects doing physical exercise none had worse and infected wounds (D grade).



Distribution of Respondent by Physical activities and healing grade

It is noticed in the present study that out of 50 population majority (30%) are using Betadine ointment, 26% of peoples using Metronidazole tablet powder and 18% are using Neosporin powder. only 6% are using Mupricon ointment and Soframycine ointment. Only 2% of subjects using Dimethicon cream, Gentamycine ointment, Sulfadiazine ointment, Clotrimazole ointment, Glycerine MgSO4 paste and Insulin irrigation

Table no. 9: Frequency and Distribution of Respondent by use topical wound care products.

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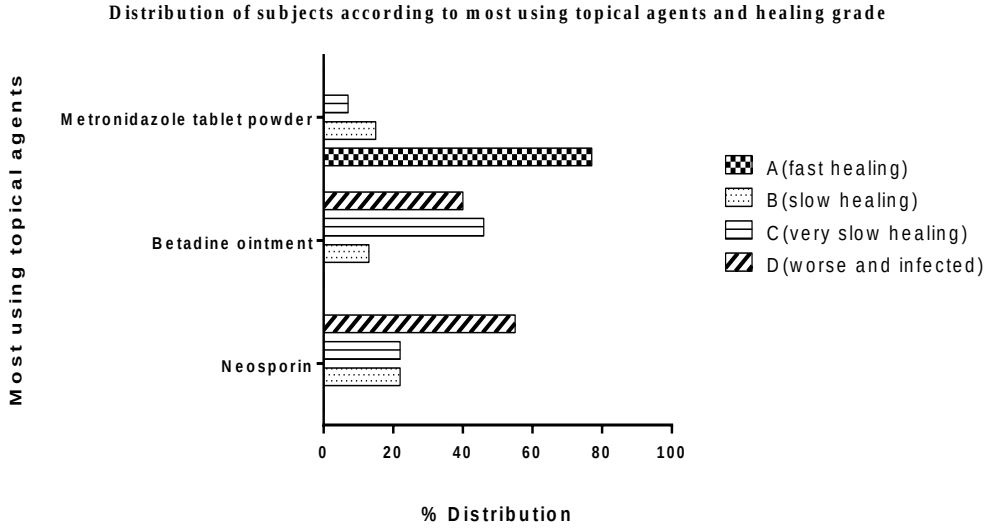
Sulfadiazine ointment	1	2
Clotrimazole ointment	1	2

Butenafine ointment	1	2
Soframycine ointment	3	6
Glycerine MgSO4 paste	1	2
Insulin irrigation	1	2

It is observed that out of 50 subjects, 30% are using Betadine ointments, 26% are using Metrogyl tablet powder, 18% are using Neosporin ointments. Among the population of Betadine ointment using subjets, 44% of having D grade wound, no one had A grade (faster healing) wound. Among the population of metrogyl tablet powder ointment using subjets, 77% of subjects having faster healing wounds(A grade), and none had D grade (worse and infected) wounds. Among the population of subjects are using Neosporin ointments, 55% of subjects having Worse and infected wounds (D geade), and none had A grade wounds (faster healing). The A grade wounds (faster healing) are absent in Betadine and Neosporin used groups.



DISCUSSION

Diabetic foot ulceration is one of the major health problems for people with diabetes mellitus, and it can result in limb loss and death. Foot ulceration is estimated to affect 15% of people with diabetes at some time in their life and 70% of healed foot ulcers recur within five years. Viswanathan et al (2000)[8] in a study in South India have observed that prevalence of foot infection was higher among rural patients (34 percent) than that among urban patients (26 percent). The present study has also shown that majority of the Diabetic foot ulcer subjects are in rural and under developed area.

Franz *et al*., 2007 and Pieringer *et al*., 2007[9], postulated that Systemic steroids cause wounds to heal with incomplete granulation tissue and reduced wound contraction. Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen are widely used for the treatment of inflammation and rheumatoid arthritis and for pain management. Calhoun JH and Cantrell J, et al. (1988)[10] state that Several antibiotics are currently used for parenteral treatment for coverage of limb-threatening and life threatening infections (cefoxitin, cefotetan, ampicillin/ sulbactam, imipenem/cilastatin, meropenem, ticarcillin/ clavulanate, piperacillin/tazobactam, levofloxacin, clindamycin, and metronidazole). Many hospitals are using a monotherapy of third-generation cephalosporins (ceftriaxone and cefotaxime). In spite of their claimed potency and wide coverage, they should be combined with clindamycin, or metronidazole especially for deep seated infections. According to Finlay IG and Bowszyc, (1996).[11] The unpleasant smell of infected foot ulcers is a distressing clinical problem known to be associated with anaerobic infection. Metronidazole gel to decrease smell from these lesions and to assess whether bacterial contamination of the tubes of gel occurs during use. In the present study also we have observed that in the majority of subjects have used Betadine ointments, Neosporin and Metrogyl tablet powder for dressing the wound. Out of total population 26% of subjects using metrogyl tablet powder packets, metrogyl infusion irrigation and normal saline solution for dressing so that their wounds are heal very fast (77% A grade wounds), none had worse and infected wounds(D grade). It has been traditional to use povidone-iodine (Betadine), acetic acid, hydrogen peroxide, and sodium hypochlorite. Most of D grade wound are founds in the population of Neosporin and Betadine using subjects.

Metronidazole exerts antibacterial effects in an anaerobic environment by the following possible mechanism**:** 5-Nitroimidazoles derivatives, such as metronidazole, tinidazole, ornidazole and secnidazole, are the drug of choice in the treatment of anaerobic protozoa. All 5-nitroimidazoles share the same mode of action. Anaerobic microorganisms reduce 5-nitroimidazoles to their active forms. This process only occurs under strongly reducing conditions. In some anaerobic protozoa and bacteria, such conditions are achieved when ferrodoxin is reduced by the fermentation enzyme pyruvate ferrodoxin oxidoreductase (POR). Ferrodoxin can transfer one electron to 5-nitroimidazole, resulting in the reduction of the nitro group. PORdoes not occur in mammalian cells. The corresponding enzyme to POR in mammalian cells is pyruvate decarboxylase, which is not able to establish a reducing potential high enough for the reduction of 5-nitroimidazoles. The reduced products of 5-

nitroimidazoles disrupt the DNA structure, thereby interfering with transcription and replication. Once metronidazole enters the organism, the drug is reduced by intracellular electron transport proteins. Because of this alteration to the metronidazole molecule, a concentration gradient is created and maintained which promotes the drug's intracellular transport. Presumably, free radicals are formed which, in turn, react with cellular components resulting in death of the bacteria. Metronidazole is active against most obligate anaerobes, but does not possess any clinically relevant activity against facultative anaerobes or obligate aerobes. In the case of diabetic foot ulcer, blood supply to the wound is less so that more number of anaerobic bacteria's are present there. the present study has shown metrogyl tablet powder dressing is more successful in wound healing, because metrogyl tablet powder containing more active ingredients than the other formulation like ointments and they act against anaerobic bacteria's in the wounds. Because of the poor blood supply the topical application of metrogyl tablet powder is more effective for diabetic foot ulcer than the oral and systemic application of other drugs.

Diabetic diet is the main treatment of diabetes to improve glycaemic control. These subjects should be actively encouraged to lose weight if they are obese. This will not only improve the diabetes control but will also reduce the pressure on the foot. Ierardi RP and Shuman CR,(1998).[12] In the present study also we have observed that, among the population of controlled diet, 41% of peoples are having faster wound healing rate (A grade wound) and 11% are having worse and infected wounds. Among the population of Un controlled diet groups, none had faster healing wounds (A grade), and 56.5% of these subjects having D grade(worse and infected) wounds.

A Cochrane review by Dorresteijn et al. (2012)[13] evaluated patient educational programmes for preventing foot ulcers, and stated educational interventions were shown to improve patients' foot care knowledge. Boulton, Holewski and Pecoraro (1990)[14] their study reveals that lack of awareness of patients and health care professionals of the risk factors for diabetic foot problems, as well as inappropriate management still lead to unnecessary morbidity and substantial health care costs. At present, standard practice usually involves the provision of unstructured and information about foot care to people with diabetes mellitus. Life-long surveillance of the feet of people with diabetes, as well as educational programmes have long been thought to reduce the incidence of foot ulcers. However, before education programmes for the prevention of diabetic foot ulceration can be widely advocated and implemented in

standard practice, there must be evidence of the effectiveness of such programmes. Education programmes for the prevention of diabetic foot ulceration can be targeted at people with diabetes and/or the health care professionals managing their care. This review focuses on the education of people with diabetes. Hamlainen (1997); Rettig (1986) and Hamlainen (1997)[15] are pointed out that, It must be stressed that foot care knowledge and patient behaviour are play an important role in healing of DFU. By the same time the present study also showing that, out of diabetic educated subjects, 35% of them having faster healing rate and only 17% of them having worse and infected wounds.

The role of the nursing care is extremely important in the management of the diabetic foot, especially in the prevention and treatment of diabetic foot ulcers. (Edmonds and Foster 1999). In this present study we have observed that, most of the faster healing grade (A grade) wounds are found in Home care Team treated subjects. The nurses play an important role in Diabetic Foot Ulcer healing. This present study describes a new practical approach to the diabetic foot, which should be helpful to all nurses who care for the patient whether in hospital or the community.

A focus on the prevention of DFS in diabetic subjects will not only improve the quality of life of those subjects but also help reduce the burden diabetic subjects place on health care systems. It is recommended that diabetic subjects engage in regular foot examinations. Higher risk individuals require foot care education regarding the avoidance of foot trauma, properly fitted footwear, smoking cessation strategies and optimization of glycemic control. Those who develop foot ulcers require management by multidisciplinary teams involving individuals specialized in diabetic foot care.

CONCLUSION

In conclusion, the knowledge and practice of foot care among DM subjects in study were poor; these were associated with illiteracy and low socioeconomic condition. The result of this study has highlighted the gaps in their knowledge and practice and underscores the urgent need for a patient friendly educational intervention coupled with regular physician reinforcement to reduce the risk of diabetic foot ulcer.

Strengths and limitations of the study

Strengths

• The scale used to measure the parameters of quality of life is validated in a sample from the same base population of DFU patients; which can improve the power/ confidence of the scale to measure the outcome measurement, the QoL.

• As the cases were interviewed in the OPD, the validity of the reported medical expenses was easy to measure.

• As the data were collected by the PI, the Inter observer variability is absent.

Limitations

• This is not a population based study. Thus it is truly representative only of those patients who come to that particular facility for care.

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