Injectable Antibiotics Market in Lower Extremity Infections : A Target Marketing Perspective

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Abstract

With the emergence of more and more local pharmaceutical companies in India, brand-launch has become extremely predicable, given that the pattern suggests one that follows suit. Many local companies are often found to be impetuous in launching their own brands of a molecule that commands a luring market size and is on its growth trajectory. The huge number of oral Rabeprazole and Vitamin D3 brands can be cited as two of the many molecules in the market today, standing as testimonies to the fact. Today, we have 484 and 648 brands of Rabiprazole and Vitamin D3 brands, respectively in the market as updated in medindia.net [Med India(2016a) and Med India (2016b)]. Such typical ideas towards executing new brand-registrations and their subsequent market-launch has left its heavy toll on companies' marketing team for the dearth of any brand differentiation. Das (2010) observed that there is an enormous gap between those companies that claim to be customer-focused and those which actually are. Hence, not much value creation - either for the doctors or their patients - is made possible by most companies. With a view to create value for the doctors, we conducted this study by focusing upon one clinical-challenge area (i.e. lower extremity infections) to recognize the clinical needs around that and ascertain if a new injectable antibiotic launch with a targeted promotion in the indication would create a lucrative niche for a marketing company. Based on our findings, we concluded that "need based target marketing" may well turn out as the game changer for pharmaceutical companies. The most significant outcome of our study was the recognition of the possible lucrative niche market for injectable antibiotics that is presented by hospitalized patients with lower extremity infections (LEIs) .

Keywords : **lower extremity infections, LEIs, target marketing, injectable antibiotics, Piperacillin plus Tazobactum, Linezolide**

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The Indian pharmaceuticals market is the third-largest in volume and nearly 70 - 80% of it is dominated by branded generics (India Brand Equity Foundation, 2015). According to India ratings, a Fitch Company, the Indian pharmaceutical industry is estimated to grow at 20% compounded annual growth rate over the next 5 years (India Brand Equity Foundation, 2015). An important characteristic that makes the pharmaceutical market in India unique is that the local players are beginning to enjoy a dominant position, which is driven by indigenous third party formulation development capabilities and early investments.

In view of the diminishing new formulation development and launch, the current trend in new brand registrations and product launches by local companies depict a pattern of following suit. The decision of new brand registrations by local and regional companies (within India) is primarily driven by basic research towards identifying the brand/formulation (within the market) showing growth (>10% CAGR) and the luring market size (>10 Crores INR) it commands. With that in background, the economic viability is then being worked out by the

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marketing companies, based upon the manufacturing access/cost as well as distribution and marketing cost. This approach to marketing has off late led to a desperate state on the ground with more than 100 companies approaching a doctor (clinician) for their share of the pie of the same formulation. Consequently, scattershot mass market sales techniques had to be adopted by sales-reps during sales-calls, striving to create value for doctors primarily through more visits, free drug-samples, and gifting: courting clients with expensive paid-up trips, meals, and the like. Many marketing gurus have described this as management decided products and push communication (Lohrey, n.d.), which is much in contrary to the proven 'need-based target marketing.' The inevitable result of the same has been the intense unfair competitions on the ground with limited value for the doctors (prescribers) as well as the patients (end users).

In this study, we began by focusing upon the clinical-needs of doctors. We endeavour to study the magnitude of one specific clinical challenge area, identifying the underlying clinical need around that, and ascertain if a new antibiotic-brand launch based upon a 'need-based target marketing' strategy would make business sense for local pharmaceutical-companies. In our knowledge, there is no other similar study being done so far to explore the doctors' clinical needs around LEI management, and the niche market opportunity (for antibiotics) presented by patients hospitalized with LEIs.

Study Objectives

The ultimate objective of this pilot study is to ascertain the indicative value of injectable-antibiotics' market presented by patients, who were hospitalized with lower extremity infections (LEIs) in two cities of North East India. The secondary objective of the study is to know if a new antibiotic brand-launch aimed with targeted promotion in lower extremity infections (LEIs) would mean creating a lucrative niche for a company.

Study Design and Methods

Considering that hospitalized patients with LEIs are mostly treated by surgeons, diabetologists, and endocrinologists, we targeted 50 doctors comprising of the above three medical-specialities from Guwahati city and Silchar town and conducted interviews with them to understand their clinical situations/experiences while they treated lower extremity infections. Additionally, we conducted surveys in 20 pharmacies to study the prescription-value of the injectable-antibiotics' prescriptions made by the above doctors in treating the disease. We conducted our field work (interviews & surveys) during June 7, 2015 to July 31, 2015.

During the personal interviews with the doctors, we collected two types of data, which are detailed below :

(i) Objective Real - Time Data : The real patients' data and the doctors' clinical situations in treating the above mentioned LEI patients during the last 30 days preceding the day of the interview.

(ii) Subjective Experiential Data: Their overall clinical experiences in treating LEI-patients over years and their expectations going forward.

During the interviews, we collected the following information with respect to the objective real-time data (of last 30 days) from each doctor : (a) name of the doctor & his/her speciality ; (b) no. of LEI patients treated in the last 30 days ; (c) no. of patients who required hospitalization (from the above pool) ; (d) names of the hospitals in which patients were admitted ; (e) degree of severity in each hospitalized patient (mild/moderate/severe) ; (f) no. of above hospitalized patients, whose diseases were induced by trauma ; (g) no. of diabetic & non-diabetic patients in the above hospitalized patients' pool ; (h) antibiotics - brand combinations used in each of those hospitalized patients ;

(i) dosage and administration route of the antibiotics used in each patient ; (j) duration of injectable antibiotics used in each patient ; (k) no. of amputations required in patients during the last one year.

Under subjective experiential data, we gathered the following information from each doctor :

(a) Average no. of patients hospitalized by the doctor per month for treating LEIs ; (b) hospitals considered for patient-admission in general; (c) antibiotics brands mostly preferred in treating hospitalized patients with LEIs ; (d) overall satisfaction rate (%) with existing antibiotics combinations ; (e) if the antibiotics selection choice was made exclusively by self or it is a multi-disciplinary choice ; (f) greatest challenges encountered in treating LEIs ; (g) expectations from pharmaceutical companies.

During our pharmacy visits, we identified the antibiotics brands prescribed by the doctors (in our panel) and ascertained the market-value of the injectable antibiotics prescribed. Based on our above work in understanding the treatment-dynamics of LEI patients, concerning the specific target customer group (surgeons, diabetologists, & endocrinologists), we have done the final compilation of all the data *to ascertain if the targeted injectable-antibiotic market presented by hospitalized patients with LEIs could represent a lucrative niche for marketing companies.*

Analysis and Results

Out of the total of 50 doctors interviewed, 47 met the criteria of being a surgeon or a diabetologist / endocrinologist. Of the 47 doctors meeting the criteria, 23 were from Guwahati city (11 general surgeons, seven orthopaedic surgeons, one foot- wound specialist, three diabetologists, and one endocrinologist) and 24 were from Silchar town (17 general surgeons, four orthopaedic surgeons, and three diabetologists).

(1) Real Time Data : The total no. of LEI-patients treated by the above 47 doctors during the last 30 days (preceding the day of our interview with them) were 419 of which 243, that is, 58% required hospitalization (Figure 1). The 243 hospital admissions were distributed across 18 different hospitals with 159 (65%) of those hospitalized patients found admitted in teaching hospitals, that is, 114 in Silchar and 45 in Guwahati. Nearly 85% of the patient-admissions due to LEIs were concentrated in four hospitals (Teaching Hospital Silchar -114 ; Teaching Hospital Guwahati - 45 ; Private Diabetes Hospital 1, Guwahati - 25 ; and Private Multi-Speciality Hospital 2, Guwahati - 19). An observable profile of the hospitals with the respective no. of LEI patients and the attending consultants with reference to this study are depicted in the Table 1.

Of the 243 patients treated in hospitals, 57% (139) of LEI patients were classified by the treating doctors as having severe infections ; 104 (43%) of the hospitalized patients were treated as having moderate infections. None of the hospitalized patients were considered as having mild LEIs (Figure 2). As expected, the majority of the patients with LEIs were diabetic. Out of the total of 243 hospitalized patients, 136 (56%) of them had diabetic foot infections. Of the above pool of 243 patients hospitalized for LEIs, 147, that is, 60% of the patients had their disease induced by trauma. Of the 147 trauma patients having LEIs, 79 (54%) were treated by orthopaedic surgeons, 66 (45%) were treated by general surgeons, & two patients (1%) were treated by the only foot-wound specialist within our panel. Twenty-two (15%) of the trauma patients with LEIs also had diabetes, which made the treatment even more challenging (see Figures 3 & 4).

During our interviews with the doctors, they preferred to disclose the generic names of the antibiotics used by them, and very few (only two) shared with us the antibiotics brands they used. We derived the market value of the antibiotics prescribed by the above doctors through our visits into the pharmacies adjacent to the treating hospitals. With regard to injectable antibiotics choices made in hospitalized patients, 228 patients (94%) were treated with multiple antibiotics combinations and only 11 (5%) patients were managed using antibiotic mono-therapy (single

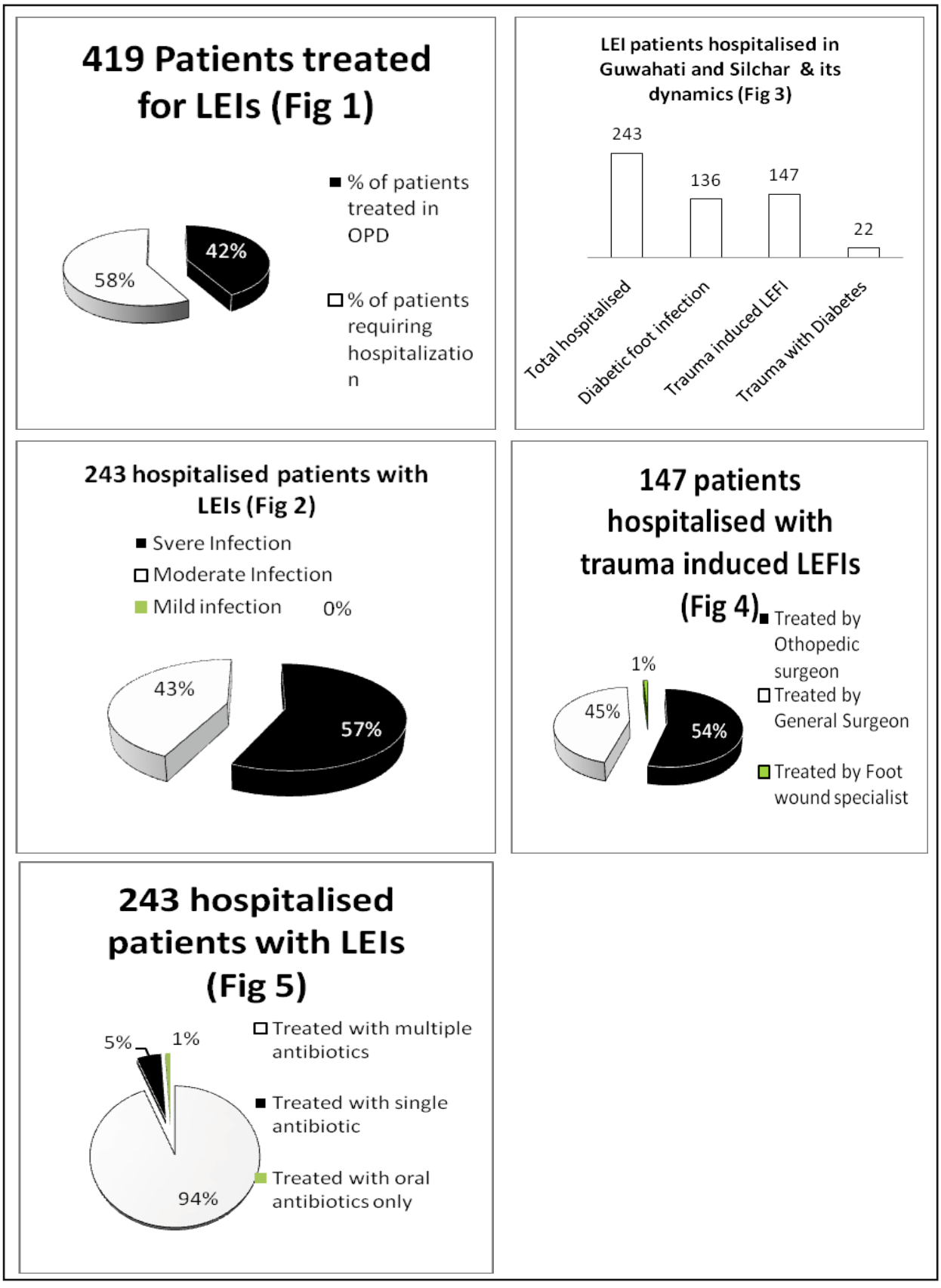

419 Patients treated for LEIs (Fig 1)
42%
58%
% of patients treated in OPD
% of patients requiring hospitalizatio n
LEI patients hospitalised in Guwahati and Silchar & its dynamics (Fig 3)
243
136
147
22
Total hospitalised
Diabetic foot infection
Trauma induced LEFI
Trauma with Diabetes
243 hospitalised patients with LEIs (Fig 2)
Svere Infection
Moderate Infection
Mild infection
0%
43%
57%
147 patients hospitalised with trauma induced LEFIs (Fig 4)
1%
45%
54%
Treated by Othopedic surgeon
Treated by General Surgeon
Treated by Foot wound specialist
243 hospitalised patients with LEIs (Fig 5)
5%
1%
94%
Treated with multiple antibiotics
Treated with single antibiotic
Treated with oral antibiotics only

Table 1. Observable Profile of Hospital Admissions for LEIs During the Last 30 Days (Preceding the Day of Interview)

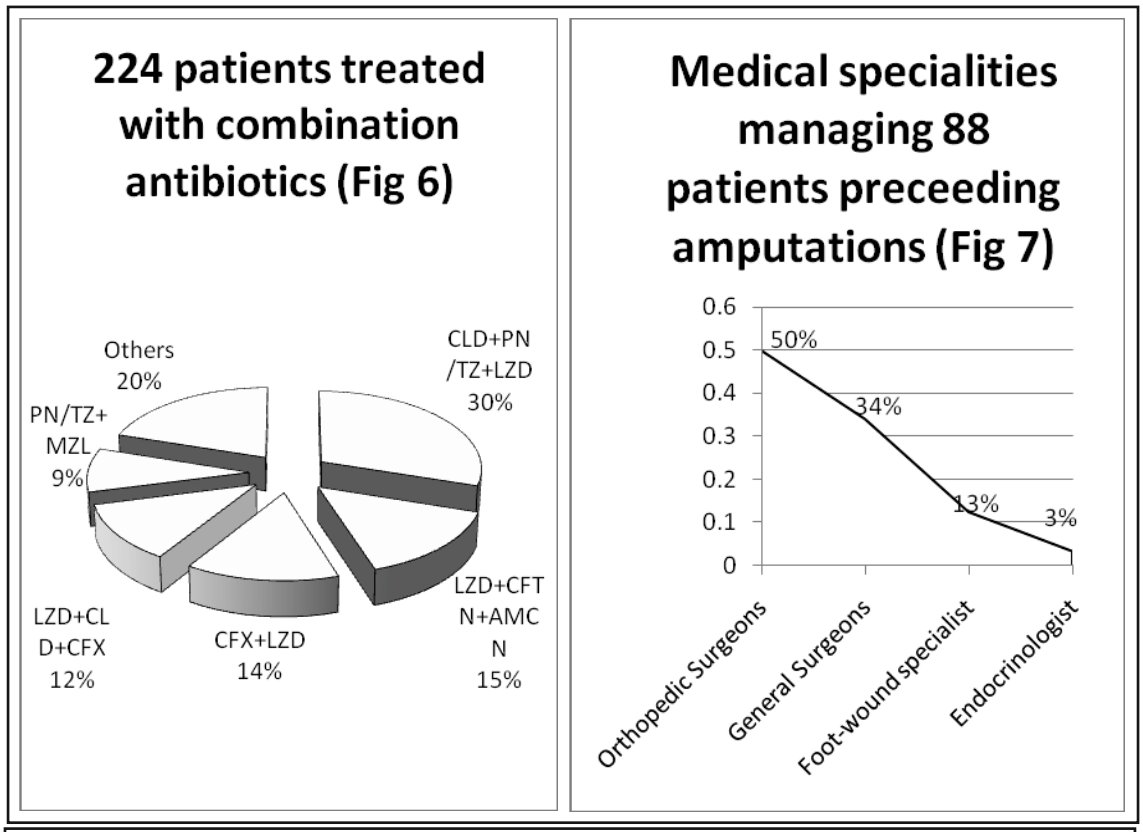
Hospital Profile	No. of patients admitted	No. of attending consultant (s)
Teaching Hospital Silchar	114	13
Teaching Hospital Guwahati	45	12
Private (Diabetes) Hospital 1 Guwahati	25	1
Private (multi-speciality) Hospital 2 Guwahati	19	1
Private (general) Hospital 3 Guwahati	6	2
Private (general) hospital 4 Guwahati	4	1
Private (multi-speciality) Hospital 5 Guwahati	4	1
Private (multi-speciality) Hospital 6 Guwahati	4	2
Private (multi-speciality) Hospital 7 Guwahati	4	2
Private (general) Hospital 1 Silchar	4	2
Private (general) Hospital 2 Silchar	3	1
Private (general) Hospital 3 Silchar	3	1
Private multi-speciality) Hospital 8 Guwahati	2	1
Private (general) Hospital 4 Silchar	2	1
Private (general) Hospital 9 Guwahati	1	1
Private (general) Hospital 10 Guwahati	1	1
Private (general) Hospital 5 Silchar	1	1
Private (general) Hospital 6 Silchar	1	1
Total	243	45

injectable antibiotic). Four (1%) of the patients were treated with oral antibiotics only (Figure 5).

Among the various injectable antibiotics combinations, injection Clindamycin plus injection Linezolide plus injection Piperacillin/Tazobactum was the most widely used during the last 30 days, with five doctors using the same in 68 patients, that is, in 30% of the patients. The other commonly used antibiotics combinations were injection Linezolide plus injection Ceftriaxone plus injection Amikacin, injection Cefuroxime plus injection Linezolide, and injection Linezolide plus injection Cefuroxime plus injection Clindamycin, which were used in 15%, 14%, 13%, & 12% of the patients, respectively (Figure 6). The various antibiotics combinations and their dosages used in the above patients are detailed in the Table 2.

Among the injectable antibiotics choices made for mono-therapy, Piperacillin plus Tazobactum were most commonly chosen and were administered in five (45%) patients. Other injectable antibiotics used as mono-therapy were Linezolide (3 patients), Ofloxacin (1 patient), Ceftriaxone (1 patient), and Cefotaxime plus Tazobactum (1 patient). However, during our pharmacy-visits, we could not find any Cefotaxime + Tazobactum brand. The most widely used injectable antibiotics were Piperacillin/Tazobactum, Linezolide, Clindamycin, and Cefuromixe. The decision to choose specific antibiotic-combinations or antibiotic mono-therapy in hospitalized patients were made irrespective of the severity of the disease and were determined more by the personal preference / habit of the treating doctors. Hence, although planned prior to the study, it was not possible to present the severity-based choice of antibiotics in our results here in this report. The above injectable antibiotic-therapy duration in LEI patients ranged from 5 days to 30 days, reflecting the magnanimous value of one single prescription generated towards treating lower extremity in hospitals. Further, during our interviews, we learnt that the uncontrollable nature of infections often required foot-amputation in those patients. During the last one year, the 47 doctors had to manage 88 patients with foot-amputations (Figure 7).

During our pharmacy-visits, we endeavored to identify the antibiotics-brands used by the doctors and derived the



Abbreviations pertaining to Figure 6 & Table 2 : CFX- Cefuroxime injection, PN/TZ- Piperacillin/Tazobactum Injection, LZD- Linezolide Injection, CLD- Clindamycin Injection, CFX-O- Cefuroxime oral, AMCN- Amikacin injection, MZL- Metronidazole Infusion, LZD O- Linezolide oral, CDM- Cefpodoxime oral, CFTN- Ceftriaxone injection, CPZ/SBT- Cefoperazone/Sulbactum Injection

value of the market created by the injectable antibiotics prescribed in treating patients with LEIs. We computed the value and the volume of the antibiotics prescriptions in LEIs that make 80% of the injectable antibiotics market in LEIs (mentioned earlier in this report). A snapshot of the antibiotics prescription value per patient over 10 days of treatment is given in the Figure 8.

We found that the market presented by the injectable antibiotics prescriptions made on the above 243 patients amounted to a total market-value of rupees four million and one fifty thousand (i.e. 4.15 million INR) over a period of 30 days.

Among the various antibiotics used, Piperacillin/Tazobactum commanded the largest market size of 1.663 million INR (over last 30 days) with a market share of 40% in hospitalized patients with LEIs. Linezolide, Cefuroxime, and Clindamycin had a market-share of 26%, 18%, & 9%, respectively (see Figure 9). The above findings are indeed significant and highly indicative of a lucrative niche presented by the injectable antibiotics market in lower extremity infections. This is because the injectable antibiotics market-value of 4.15 million INR, which we found over a period of 30 days, implies a humongous underlying potential of about fifty million INR (49.8 million INR) annually (see Figure 9). Additionally, the above annual market of 49.8 million INR is created by the prescriptions made merely by 47 doctors from only two cities.

To substantiate our objective findings, we had decided (prior to the study itself) to also collect subjective experiential data from all the doctors in our panel. The details are outlined as follows :

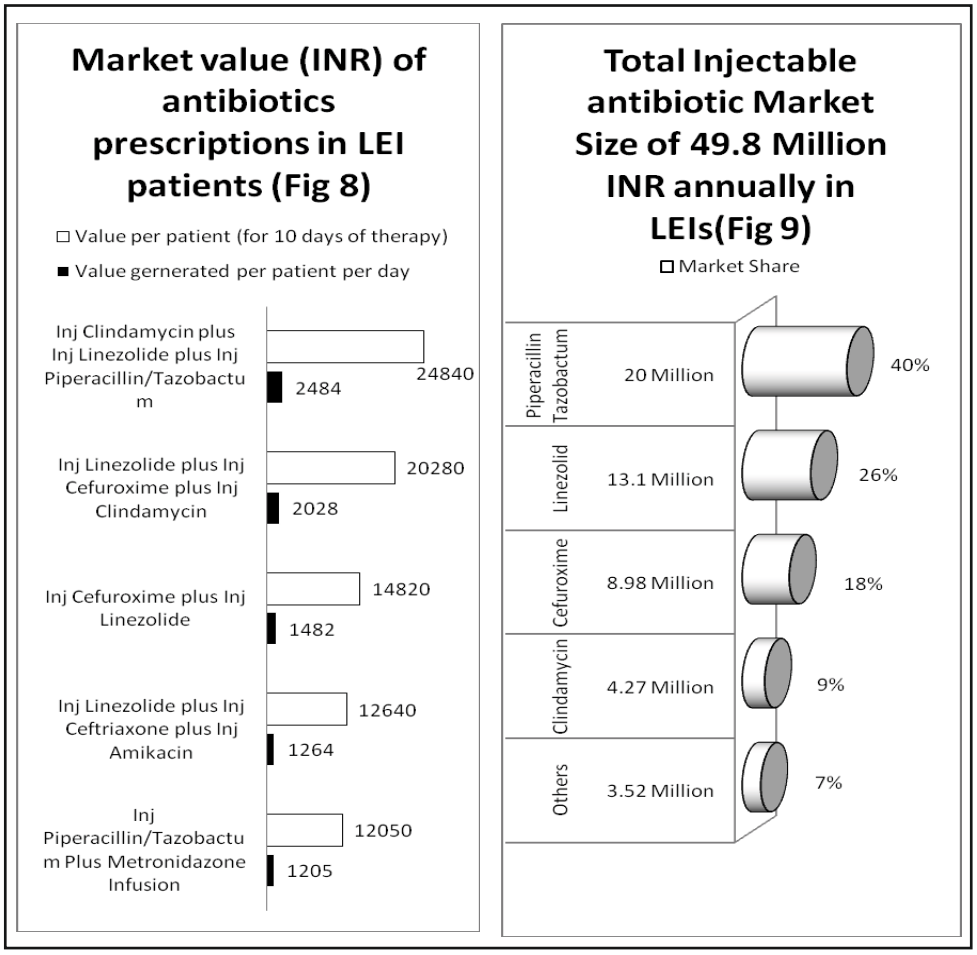
(2) Subjective Experiential Data : To rule out the possible chance-findings in terms of the occurrence of LEI

Table 2. Antibiotics Combination & Dosages Used in Patients During the Last 30 Days

Antibiotics combinations in LEIs	Dosage and administration	Duration range	No. of Doctors using the combination	No. of patients
Inj Clindamycin plus Inj Linezolide plus Inj Piperacillin/Tazobactum	CLD- 600mg BD IV, LZD- 600 mg BD IV, PN/TZ- 4.5 GM QID IV	7-30days	5	68
Inj Linezolide plus Inj Ceftriaxone plus Inj Amikacin	LZD-600mg BD IV, IV, CFTN-500mg BD IV, AMCN-250 mg BD	5-10 days	2	33
Inj Cefuroxime plus Inj Linezolide	CFX-500mg BD IV, LZD- 600mg BD IV	7-15 days	4	32
Inj Linezolide plus Inj Cefuroxime plus Inj Clindamycin	LZD- 600 mg BD IV, CFX-500mg BD IV, CLD- 600 mg BD IV	7 days	2	30
Inj Piperacillin/Tazobactum Plus Metronidazone Infusion	PN/TZ- 4.5 GM QID IV, MZL- 100 ml TID	10-15 days	2	20
Inj Linezolide plus Inj Piperacillin/Tazobactum	LZD- 600 mg BD IV, PN/TZ- 4.5 Gm QID IV	5-10 days	2	13
Inj Linezolide plus Inj Clindamycin	LZD- 600 mg BD IV, CLD- 600 mg BD IV	10-15 days	3	7
Inj Ceftriaxone Plus Inj Amikacin plus Clindamycin	CFTN- 500 mg BD IV, AMCN- 500mg BD IV, CLD- 600mg IV BD	10 days	1	4
Inj Linezolide plus Cefuroxime oral	LZD-600 mg BD IV, CFX-O-500mg BD	7-10 days	1	3
Inj Linezolide plus Inj Amikacin plus Metronidazole Infusion	LZD-600mg BD IV, AMCN-250 mg BD IV, MZL- 100ml TID	10-15 days	1	3
Inj Cefoperazone/Sulbactum plus Inj Piperacillin/Tazobactum plus Linezolide Oral	CPZ/SBT- 2 Gm BD IV, LZD O- 600 mg BD , PN/TZ- 4.5 GM BD IV	10-15 days	1	3
Inj Amikacin plus Metronidazole Infusion	AMCN- 250 mg BD IV, MZL- 100 ml TID	7 days	1	3
Inj Clindamycin plus inj Amikacin	AMCN- 250 mg BD IV, CLD- 600 mg BD IV	10 days	1	2
Inj Linezolide plus Cefpodoxime oral	LZD-600mg BD IV, CDM -200 mg BD	7 days	1	2
Inj Cefuroxime plus Inj Clindamycin	CFX-500mg BD IV, CLD- 600mg BD IV	10 days	1	1
Total			**28**	**224**

Abbreviations pertaining to Table 2 : CFX- Cefuroxime injection, PN/TZ- Piperacillin/Tazobactum Injection, LZD- Linezolide Injection, CLD- Clindamycin Injection, CFX-O- Cefuroxime oral, AMCN- Amikacin injection, MZL- Metronidazole Infusion, LZD O- Linezolide oral, CDM- Cefpodoxime oral, CFTN- Ceftriaxone injection, CPZ/SBT- Cefoperazone/Sulbactum Injection

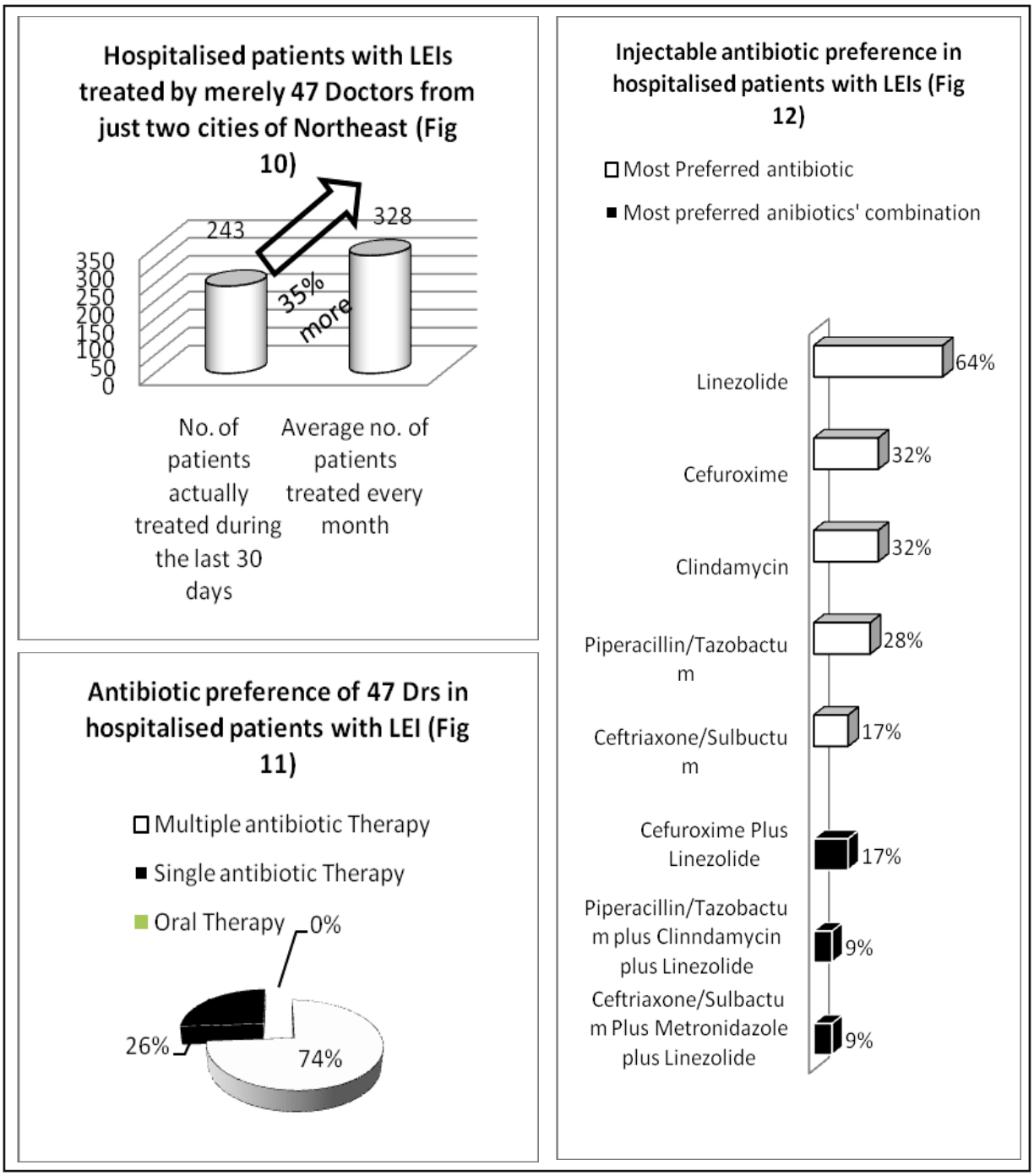
Abbreviations pertaining to Table 2 : Inj- Injection, IV- Intravenous, BD- Twice a day (every 12 hours), TID- Thrice a day (every 8 hours), QID- Four times a day (every 6 hours)]



events reported by each doctor with respect to the 30 days, we sought additional information from each doctor in terms of the average no. of hospitalized patients with LEIs treated by him/her per month over the period of last one year. The average no. of hospitalized patients with LEIs treated by the 47 doctors per month were 328, which is 34.9% higher than the actual no. of LEI patients treated during the last 30 days (preceding the day of the interview) (Figure 10).

This is a highly significant finding for it reinforces the availability of the humongous injectable antibiotics market in LEIs we found earlier (i.e. the market size of 49.8 million created by merely 47 doctors from just two cities of North East). The hospitals which they usually considered for admitting LEI patients are similar to what we found for patients being admitted during the last 30 days (Table 1), with just one exception, that another private hospital of Guwahati also featured in the preference of one of the general surgeons. The data also reinforces our earlier findings (real-time data) suggesting that more than 50% of the LEI patients were treated in teaching hospitals, both in Silchar & Guwahati.

With regard to the choice of injectable antibiotics, 35 doctors, that is, 74% expressed their preference to use combination-therapy (multiple antibiotics) rather than a mono- therapy (single antibiotic) in their hospitalized patients. Oral antibiotics are used only as a follow-up therapy post discharge (see Figure 11). Among the doctors using multiple-antibiotics therapy, 50% (17) of them preferred using triple drug combination. Injection Linezolide plus injection Cefuroxime was the most widely preferred injectable antibiotic combination followed by injection Piperacillin/Tazobactum plus injection Clindamycin plus injection Linezolide and injection Ceftriaxone/Sulbactum plus Metronidazole Infusion plus injection Linezolide (Figure 12).



We also discussed with the doctors about their satisfaction rate with the existing antibiotics and their greatest challenges in treating LEIs. The overall satisfaction rate with the existing antibiotics ranged from 60% to 100% ,with the average satisfaction rate of the panel being 82.55%. From a behavioural-economics view point, this implies having an unmet need at the psychological level of the respondents, creating more opportunities for target marketing in this clinical area.

Another important insight that we discovered from this study is that only 36% (17) of the doctors decided their choice of antibiotics based upon a multi-speciality partnership in their hospital. This is much in contrary to the

international recommendations (Longo, 2012). Hence, our next set of questions, concerning the greatest challenges faced by the doctors while treating LEIs, became even more relevant. We discovered 16 important clinical challenges faced by doctors while treating patients with LEIs (Figure 13).

Among the various challenges, the following 10 (in order) were found to have the greatest weightage :

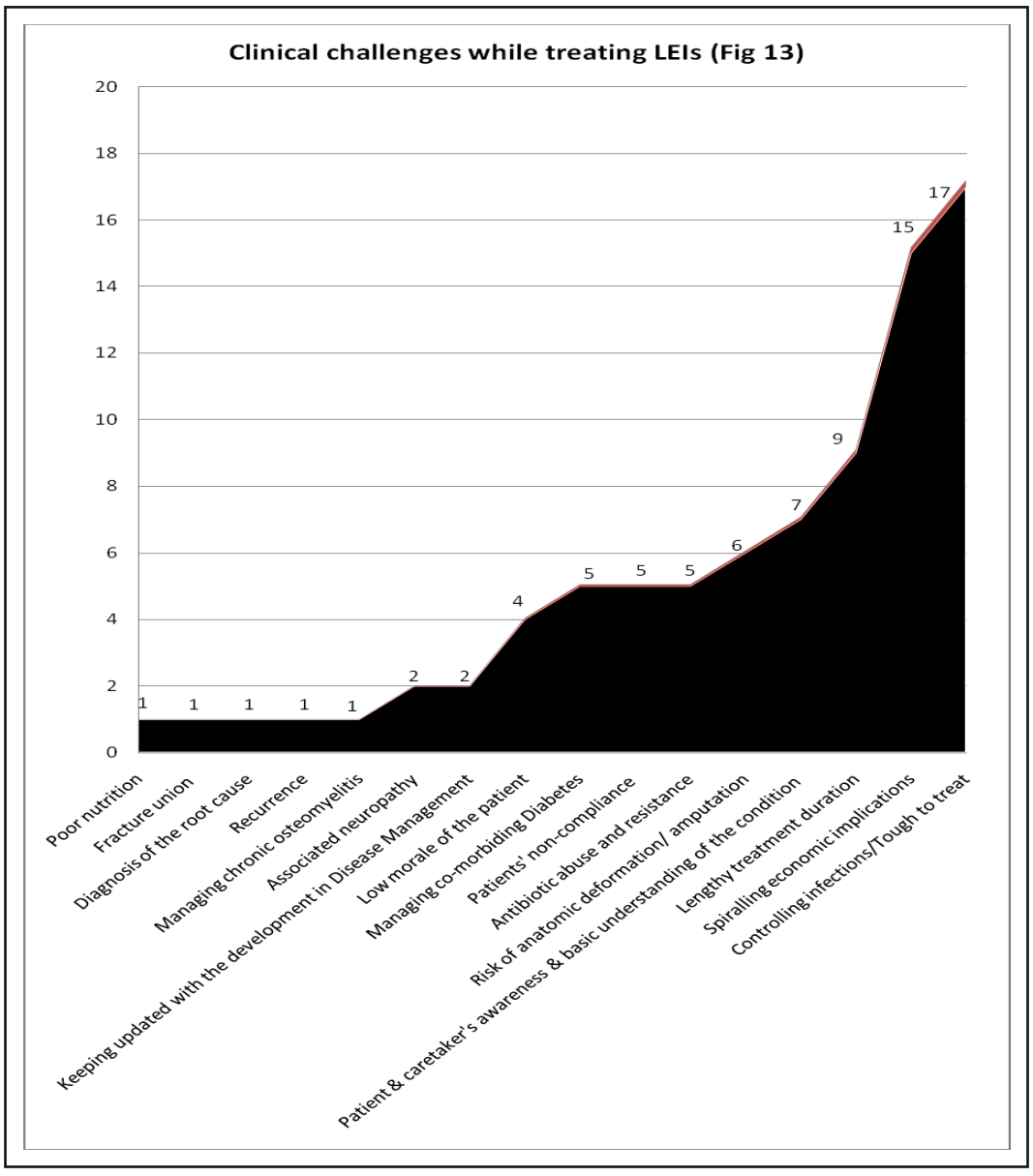
(i) Controlling infections (Tough to treat nature of infections),

(ii) Spiralling economic implications,

(iii) Lengthy treatment duration,

(iv) Patient & caretaker's awareness and basic understanding,

(v) Risk of amputation,



(vi) Antibiotic abuse and resistance,

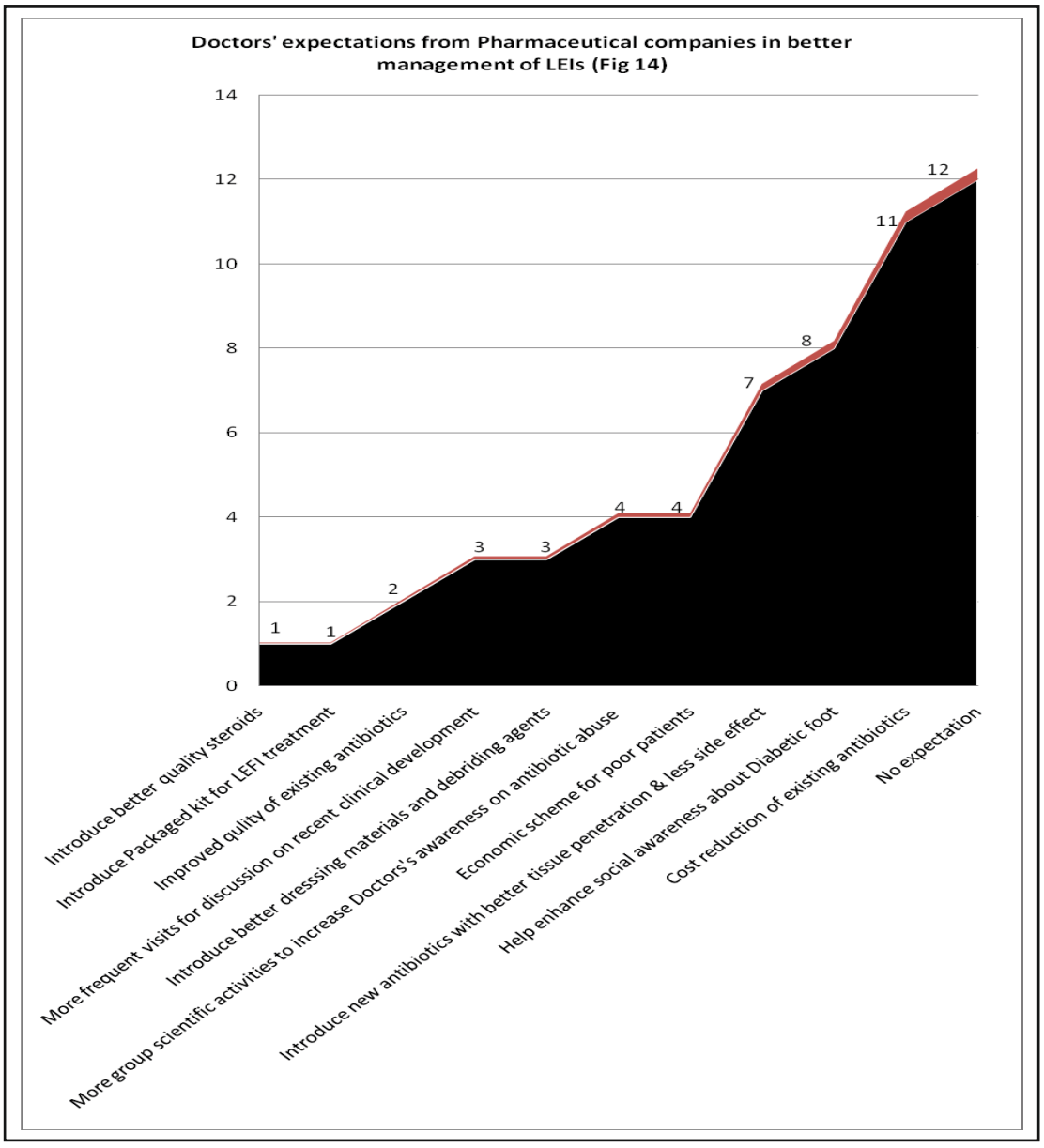
(vii) Patients' non-compliance,

(viii) Managing diabetes,

(ix) Low morale of the patient,

(x) Keeping updated with the developments in disease management.

Anticipating the above scenario prior to the study, we planned out our last set of questions towards discovering the doctors' expectations from the pharmaceutical companies to address the clinical challenges in treating lower extremity infections (LEIs). While we initiated the discussions towards understanding the doctors' expectations from pharmaceutical-companies, we were quite astonished to discover that 26% (12) of the doctors did not wish to keep any expectation from their pharmaceutical partners. This was indeed very striking, which in our mind was the



opening of the Pandora's box, reinforcing that something needs to done differently fast by majority of the pharmaceutical-companies so as to restore their credibility in being trusted contributors to the medical community. Some of the answers towards that could be unearthed from the inputs we received from the other doctors, who were kind to express their expectations.

During our interviews, we discovered 10 important expectations that doctors have from their trusted pharmaceutical partners while managing LEIs. The same (with their respective weightages) are detailed in the Figure 14.

The five most important support-areas (in order), which according to the treating doctors, are expected out of the pharmaceutical-companies in the space of LEFIs are :

(i) Cost reduction of existing antibiotics.

(ii) Activities to enhance social awareness of diabetic foot.

(iii) Introduce new antibiotics with better tissue penetration & fewer side effects.

(iv) Economic scheme for poor patients.

(v) More group scientific activities to increase doctors' awareness on antibiotic abuse.

We believe that every input provided above would go a long way towards enabling any company that is planning to explore the LEI market with their existing or forthcoming injectable antibiotic formulation(s). As an illustration, the first expectation about having a reduced cost of the existing antibiotic therapy may well be achieved when the company has in the core of its marketing strategy, the plan as to how they would enable a treating physician with a multi-disciplinary partnership, setting antibiotic protocols and thereby ensuring early eradication of infection by way of evidence-based practice. This would, in turn, result in a reduced duration of treatment, thereby ensuring much reduced cost of therapy. Additionally, this would also address another impending challenge, which haunts the treating doctor in the form of lengthy treatment impeding positive motivation of the patients as well.

Discussion

Market analysts across the globe are keenly watching the Indian pharmaceutical business, given the high (20% CAGR) growth the industry is poised to deliver over the next 5 years (India Brand Equity Foundation, 2015). According to experts, if players want to maintain leadership, they cannot limit their focus only to increasing share in the existing markets. Instead, they would need to constantly anticipate and shape the evolution of the market (McKinsey & Company, 2015).

Considering that not many players are currently embarking upon a focused promotion of its antibiotics portfolio in lower extremity infections (LEIs) as its core strategy, unlike in indications such as intra-abdominal infections, respiratory tract infections, bloodstream infections, etc., and that 85% of lower limb amputations are preceded by lower extremity foot ulcers and infections (Gupta, 2012), we endeavoured to study the magnitude of the clinical burden presented by hospitalized patients with LEIs. Our focus was to explore if positioning a new injectable antibiotic in LEIs would contribute in building a powerful brand. As substantiated by many market observers, customers will pay a substantial premium for a go brand and remain loyal to that brand (Reddy & Muniraju, 2009). With the above in view, we took up this study to aid local pharmaceutical companies make marketing decision with respect to investing in the LEI market for building a powerful antibiotic brand. *In our knowledge, there is no other interview-based study that has been done so far to explore the doctors' clinical situation around LEI management, and the niche market opportunity (for antibiotics) it presents.*

In this study, we worked to recognize the clinical circumstances around LEIs treated in hospitals, and we discovered a humongous market of about fifty million INR annually (50 mn annually) emerging out of the same

(Figure 9). The LEI market we are discussing could even be much greater, for the subjective experiential data indicated it to be bigger by an additional 35% (Figure 10). *Our results further establish our anticipation that general surgeons, orthopaedic surgeons, diabetologists, and endocrinologists form the core target-audience in LEIs market.* Additionally, the pressing need of more effective injectable antibiotics in treating hospitalized patients with LEIs were further pronounced by the fact that almost 60% of the patients presented with severe infection and not a single patient admitted had mild infection (Figure 2).

Considering that the clinical challenges often go up manifold because of co-morbidity with diabetes and other inducing conditions due to trauma (Figure 3), with the frequent need for amputations (Figure 7), it throws open excellent opportunities for pharmaceutical companies for long-term knowledge based customer relationship management by aligning their marketing communications and activities focusing upon disease management.

We also found that a majority (94%) of the LEI patients treated during the last 30 days were considered for multiple-antibiotics combination therapy and the most commonly used antibiotics combination during the last 30 days involved three high-antibiotics (Piperacillin/Tazobactum plus Clindamycin plus Linezolide) for up to a period of 30 days. *For us, it reinforces the huge clinical challenge we discussed earlier and also points out towards the high value per prescription per patient.* The average value generated by each patient treated with the above antibiotic-combination amounted to INR 24,840. In our study, we discovered that the minimum value that is generated by injectable antibiotics combination therapy in more than 80% of the patients amounted to INR 12,050 (Figure 8) . *This implies the augmented value potential of the injectable antibiotic portfolio in LEI-indication for companies and also re-emphasizes the importance of targeting the right set of doctors who treat LEIs in hospitals.* In on our study, we found that 65% of such patients are treated in teaching hospitals, which holds true for both the cities/towns. *Hence, based upon our study, we believe that general surgeons, orthopaedic surgeons, diabetologists, endocrinologists, & foot wound specialists who are associated with hospitals (particularly teaching hospitals) present as a lucrative target group in this market.*

In this study, under objective as well as subjective data, *we found that Piperacillin/Tazobactum, Linezolide, Cefuroxime, & Clindamycin were among the top injectable antibiotics considered for they captured >80% of the prescription market in LEI hospitalized patients (Figure 9 and Figure 12). This indicates an opportunity for pharmaceutical companies to command a premium per unit in this market, when they explore this market with their new launch. From our pharmacy visits, we derived that the per unit retail price of the brands of the above mentioned antibiotics ranged from INR 282 to INR 499.*

What is interesting and important to note here is that despite employing multiple-antibiotics therapy and having availability of so many antibiotic-brands, doctors are constantly challenged by the tough to treat nature of the disease, and controlling infections still remains as the biggest challenge in treating LEIs. In addition, the spiralling economic implications, with the high risk of amputation and antibiotic resistance in these patients clearly brings into sight the deep latent need of the medical community for a potent antibiotic and the commitment of a much trustworthy knowledge-based partnership from the pharmaceutical industry. These, in turn, present a huge market opportunity for companies that explore the LEI market with targeted promotion of specific injectable antibiotics in lower extremity infections.

Based on our findings during the above study, we conclude that 'need based target marketing' may well be turned out as the game changer for pharmaceutical companies, for the same paves way for an 'outside-in-outside approach,' [1] thereby helping make important marketing decisions based upon the needs of the targeted doctors' groups. We believe that the most significant outcome of our study has been the recognition of the indicative

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[1] 'Outside-in-outside' approach refers to systematic decision making process in marketing, where a marketer first looks to gather relevant inputs from customers' experiences in the market (i.e outside) and then reflects, ponders, and dissects upon that within his/her mind to develop a product solution and strategies (i.e in) and accordingly delivers the product solution for the customers into the market (i.e. Outside).

lucrative niche market for injectable antibiotics that we discovered as presented by hospitalized patients with lower extremity infections.

Managerial Implications

Our study indicates managerial implications at three levels as outlined below :

(1) Market Strategy : Based on the potentially humongous market opportunity presented by LEI patients and the prudence to work towards shaping the market-evolution, it presents a managerial decision to further explore the width and depth of the LEIs market across geography through deeper market research. An additional implication for the manager (market strategy) includes evaluating options to make the most suitable injectable antibiotic formulation available for LEIs on the basis of scientific evidence, manufacturing access, and business-economics study. Further, it would be interesting to evaluate how the existing antibiotic portfolio of a company might get enriched and impacted, while a company taps the LEI market opportunity.

(2) Brand Strategy : With the company deciding to launch or position an injectable antibiotic brand to tap the LEI market opportunity, it becomes imperative on the part of a brand manager to address 'whom to see?,' 'where to sell?,' 'why to sell?,' and 'How to sell?' Our study does provide interesting insights addressing some of the above vital questions. The study clearly reinforces orthopaedic surgeons, general surgeons, diabetologists, endocriologists, & foot-wound specialists being the primary target-audience for the brand promotion, and hence, the brand manager may develop the brand communication keeping the above five categories in mind. Additionally, our study also emphasizes that the brand offers greatest selling opportunities in teaching hospitals and diabetes hospitals. This implies that a brand manager collaborates with the field-sales management to work out a coverage list of doctors in such hospitals before hand, across geography, to freeze development of promotional inputs and budgets for the brand-launch and thereafter, considering that the study also illustrates that about 57% of the hospitalized patients had severe infections, a brand manager would be keen to tap the opportunity to augment value by promoting the high-dose of the antibiotic brand for longer duration than usual. The study also points out an opportunity to launch an oral extension of the brand for follow-up therapy, thereby significantly enhancing the brand value. Finally, our study also gives vital insights towards developing a brand-promotion strategy focusing upon the advantages of the new antibiotic over Piperacillin/Tazobactum, Clindamycin, Cefuroxime, and Linezolide. At the same time, the study indicates an existing gap in fulfilling doctors' expectations and meeting the clinical challenges. This insight clearly offer opportunities for brand managers to work out a suitable strategy to help the field-sales team better manage "customer relationships" and develop "key opinion leaders" through scientific partnerships with the medical fraternity.

(3) Field Sales : Based on the above, it is imperative on the senior leadership team (overseeing the field-sales-force) to work out the customer coverage norms for the field-force in making field visits to the target-doctors & hospitals category and develop a coverage matrix for ongoing monitoring. Additionally, as 56% of the hospitalized patients in this study had diabetic foot infection, it implies that the senior leadership invest to develop and organize learning interventions for the field force, so as to help them become aware of the unique challenges faced by doctors in treating diabetic foot infections. This will enable the field force to have meaningful interactions with their target doctors and develop long term relationships.

Limitations of the Study and Scope for Further Research

Considering that this was a pilot study involving a small sample of only 47 respondents (doctors) from merely two geographical markets, the work is limited in its power to be called well-conclusive. Further, there is no similar study done in the past targeting doctors' clinical needs around LEIs and because the data points out toward a lucrative antibiotic-niche market of about 50 million INR (annually) in just two cities/towns, this study indicates much scope and need, thereby reinforcing the value of conducting similar studies with a larger sample size to enable making of prudent and major marketing decisions by companies.

Additionally, in our opinion, the scope for further research in this arena includes conducting a follow-up study by evaluating the magnitude of the disease burden and the consequent market size by collecting real-time patient data from the indoor wards of the hospitals, followed by interviews of the treating physicians. This would possibly pave way to have a well-conclusive evidence of the existing market opportunity for injectable antibiotics in LEIs.

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