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Eapen, Bell R

Kaya Skin Clinic

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Title:

Research in Cosmetic Dermatology: Reconciling medicine with business

Author:

Bell Raj Eapen MD.

Affiliation:

Kaya Skin Clinic

Dubai, U.A.E.

Address for correspondence:

Dr. Bell Raj Eapen

Specialist Dermatologist

Kaya Skin Clinic

P O Box: 50394

Dubai, U.A.E.

Phone: 00971 4 3369082

Fax: 00971 4 3369083

Email: admin@dermatologist.co.in

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Abstract:

Cosmetic dermatology is a marriage between medicine and business. Research in cosmetic dermatology shares the fundamental principles of clinical and pharmaceutical research. Research team can help the decision makers by giving a realistic picture of the uncertainties involved. Certain mathematical models and market research techniques can aid decision making.

Keywords:

Research, cosmeceutical, decision making

Introduction

Cosmetic dermatology is a unique specialty where clinical medicine has a legitimate but often detested relationship with business. There are people lined up on either side of the hazy line between medicine and business, each group trying to understand the other. True clinical dermatologists consider cosmetic dermatology an imprecise and vague specialty.(1)

A cosmeceutical, is conventionally defined as a cosmetic product claimed to have drug-like properties.(2) The term cosmeceutical is a portmanteau of the words "cosmetic" and "pharmaceutical" and is not recognized by Food and Drug Administration (FDA). A cosmeceutical is not subject to FDA review and approval processes.(3) Medical devices used in cosmetic dermatology range from cautery machines to lasers. Injectable enhancement products like Botox®(4) and dermal fillers are also popular. The Division of General, Restorative and Neurological Devices (DGRND) within FDA regulates most of the medical devices and injectable dermal fillers used by dermatologists.(5) In this article the term "cosmeceutical" is used to represent cosmetic products, injectable products and medical devices (like microdermabrasion and laser machines) used in cosmetic dermatology.

The pharmaceutical research paradigms of target identification, screening, lead optimization and clinical trials from phase I to IV do not directly apply in cosmeceutical research.(6) In pharma the industry decides what is good for the patient where as in cosmetic dermatology the patient decides what is good for him/her. Hence it is not imperative that a significant placebo effect be identified and accounted for even if it arises from a dominant bias. A typical example is Laser Hair Reduction. It is very difficult to conclusively prove that it is more effective than any other hair removal method to justify its cost. But it is a billion dollar industry and is considered a ‘successful technology’ in cosmeceutical arena.(7)

This article is an attempt to reconcile research in cosmetic dermatology with business and market research. First we discuss the basic requirements for clinical research in cosmetic dermatology. Then we move on to the uncertainties faced by decision makers and the mathematical models which may be of help in solving them. Finally we briefly discuss the market research techniques used in cosmeceutical industry.

Requirements for research in cosmetic dermatology

The term research has a different meaning in cosmeceutical industry. Some big organisations use the term for product or service improvement. Optimization of existing technology for specific needs

(not necessarily different indications) is a common practice in cosmeceutical industry. Each organization conducts its own research for optimizing the technology. As this is often conducted without a proper understanding of clinical research paradigms, certain errors of judgment are frequently encountered.

THE NEED TO COMPARE

It is always worthwhile to compare new technologies to already available ones in terms of efficacy and adverse effects. For example several depigmenting agents are known with varying levels of efficacy. When a new and more expensive product combination is introduced, it is important to compare it with individual components used alone to justify the cost of the combination. However the decision of whether to adopt a new technology should not be based entirely on the results of comparison. But the comparison will give clear indications about the likely success and the potential problems during introduction and has substantial marketing value.

THE NEED TO RANDOMIZE

Randomization is given due importance in pharma trials. But many cosmeceutical researchers rely on a 'study group cohort' rather than random sample. The active ingredient, vehicle or even contaminants in a cosmeceutical can cause an allergic or irritant reaction in a small percentage of users.⁽⁸⁾ Manufacturers try to assess the risk during the trial period. If the trials are conducted on the same group always, the

group undergoes a natural selection process as those who develop a reaction are unlikely to report for further trials. The results on this 'thick skinned' cohort cannot be reliably extended to the general population.

THE NEED FOR BLINDING

Blinding is another important concept often ignored in cosmeceutical research. Sometimes blinding can be difficult or impossible to implement especially for those trials involving machines. Hence most of the studies are plagued by researcher as well as subject bias. This bias gets confounded several times when the researchers also become part of the study group, a practice common in cosmeceutical research. Individual service providers often comment that they have tried the product or service on themselves and found it to be safe and effective. Having an independent blinded observer who does majority of assessment can significantly reduce the bias. But bias cannot be completely removed from study design in cosmeceutical research and should be kept in mind during final evaluation.

THE NEED FOR OBJECTIVE ASSESSMENT

The assessment is often subjective in cosmeceutical research. The unavoidable biases along with subjective assessment methods make the studies less credible. It is important to make full use of new, objective assessment techniques involving computer assisted image analysis and optical spectroscopy. Computer assisted image analysis is the

computational extraction of meaningful information from digital images by pattern recognition and digital geometry.(9) Optical spectroscopy involves study of scattering and reflectance pattern of the skin for an objective assessment of appearance. (10)

THE NEED TO USE MOLECULAR AND CELL BIOLOGY TECHNIQUES

The chance of success for a cosmeceutical is likely to be higher if it has a strong basis in molecular and cell biology. Ingredients developed on the basis of its effect on well characterized molecular targets are more likely to be successful. The new generation growth factors and aquaporin modulators are typical examples.(11) The recent developments like in vitro human skin helps in assessing the efficacy and adverse effects of cosmeceuticals in a more objective and safe way.(12)

THE NEED TO CONSIDER SKIN AND LIFE-STYLE VARIATIONS

The importance of skin type in the choice of cosmeceuticals is well known. Certain lasers are considered not safe on darker skin as the chances of developing adverse effects are more.(13) The environment and life style can also have a significant effect on skin biophysical characteristics. Hence it is important to account for these confounding factors in study designs especially for those cosmeceuticals promoted as suitable for all skin types.

THE NEED FOR LONG TERM FOLLOW-UP

Since cosmeceuticals are not strictly regulated, products are introduced based on studies conducted for a few days or weeks or at most a few months. Since a watchdog like FDA is not present, certain technologies are introduced into the market without enough studies to back the safety claims of manufacturers. Often the user is not even aware of this fact. Permanent dermal fillers are a typical example.(14) It is known that foreign bodies can elicit a tissue reaction after prolonged periods of exposure. Hence short term safety of dermal fillers does not guarantee its long term safety after several injections. Long term follow-up studies are lacking for many dermal filler materials. The same applies to other techniques like laser as well.

Uncertainties in decision making

Once the researchers estimate the efficacy and safety of a cosmeceutical it is the turn of the decision makers to decide when, where and how to introduce the product in the market. The researcher, who is only aware of the net present value of the solution he offers, sees any delay in introduction as a strategic mistake. However the decision makers have to cope with the limitations of this approach and have to deal with several uncertainties. The researcher can be of assistance in gauging these uncertainties. The next section deals with

certain techniques for decision making in the context of cosmeceuticals.

THE TECHNOLOGY UNCERTAINTY

In simple terms 'technology uncertainty' means today's gold standard may not be the ideal option tomorrow. For example the fractional technology superseded many existing laser technologies for a variety of indications.(15, 16) It is difficult to predict the viable life span of an existing technology. However a critical inspection of the evolution of the technology gives valuable hints to this. For example laser is a technology with high level of uncertainties where as an AHA peel is a more stable technology with only minor modification over a period of time.

THE MARKET UNCERTAINTY

The success of a technology depends not just on the efficacy and safety of the product, but also on a variety of other market related factors like cost, availability, ease of administration and advertisements. There are restrictions on advertisement for certain technologies in certain places. The insurance companies also add to this type of uncertainty. Any decision by an insurance company to reimburse a particular technology will tilt the balance in its favour.

THE COURSE UNCERTAINTY

Keeping track of the long term safety of cosmeceuticals is important. However researchers in cosmetic dermatology have the habit of assuming long term safety based on few instances of safe use. The research team should be able to give a frank estimate of encountering an exception to the decision makers. This will prevent the decision makers from being Bertrand Russell's inductivist turkey. This fable relates the 'error of induction' to that of a turkey, fattened by its owner, is led to believe in the persistence of its life of prosperity, only to be slaughtered at Christmas.

THE COMPETITION UNCERTAINTY

When an organization plans the adoption of a new technology, it is important to consider how easy it would be for the competitors to acquire the same technology. Successful technologies will be quickly adopted by competitors thereby reducing the revenue from the particular stream. Competition uncertainty is low with new inventions which can be patented. Hence large organizations should promote inventions though novel inventions seldom happen. Novelty factor is important in cosmeceutical industry as new technologies tend to fetch more revenue initially. But it is important not to project initial success to future.

THE SOCIAL UNCERTAINTY

The social uncertainty is an important factor in cosmeceuticals. A shift of social concerns can affect the popularity of certain cosmeceuticals. The increased awareness of the carcinogenic potential of UV has made sunscreens extremely popular while the popularity of tanning products has decreased with time. The depigmenting 'fairness' solutions are very popular in certain parts of the world.

THE MANPOWER UNCERTAINTY

Manpower uncertainty refers to the uncertainties in providing staff training or uncertainties in acquiring sufficiently trained personnel. Certain technologies which are training intensive tend to have more steps and are difficult to be standardized. Large providers try to maintain a six sigma quality for consistency in cosmetic service delivery. 'Six sigma' is a statistical concept which implies that if variations are kept to a minimum, few services fail to meet specifications. (17)

Mathematical Models for decision making

The above mentioned uncertainties make the decision makers' job difficult. The research team can chip in by providing a fair assessment of the above uncertainties. Though decision making to a great extent is intuitive and comes from experience, there are certain objective techniques which may be of significant help.

HOW TO DELAY: THE REAL OPTIONS PARADIGM (18)

The uncertainties can be reduced by delaying the exercise of an option. 'Real options' is a technique to mathematically evaluate the worth of initiating, abandoning, slowing down or speeding up the introduction of a cosmetic. 'Real options' is based on the option pricing theory and is traditionally used in the trading of stocks. It can also be used in comparing the worth of two or more solutions (portfolio of options) for the same concern to decide which one to pursue. Any further discussion of Real options is beyond the scope of this article.

HOW TO COMPETE: THE GAME THEORY PARADIGM (19)

Game theory is a branch of applied mathematics to analyse strategic situations, in which an individual's success in making choices depends on the choices of others. As far as competing with other providers are concerned, it may be appropriate to have a 'cooperative game' model with each concentrating on their area of expertise rather than encroaching on competitors area of expertise. For example if your existing competitor specialises in invasive techniques like Botox® or fillers, it may be better to concentrate on other niche areas like laser.

HOW TO PRIORITIZE: THE BAYESIAN PARADIGM (20)

A modified Bayesian probabilistic model called 'influence diagrams' can be useful for solving decision-making problems. Influence diagram

graphically represents decisions, uncertainties and objectives and their connections and is a compact representation of a decision tree. It can help the decision maker to effectively communicate with the research team and to prioritize steps to maximise value.

The simple influence diagram depicted in **figure 1** represents the summary of what we have discussed so far. The success of the clinical research influences the decision to launch a product or service along with the competition and market uncertainties. All these factors influence the market value.

Market Research for decision making (21)

Understanding the market and subsequent regular monitoring of market trends are very important for decision makers. Qualitative and quantitative techniques can be used for market research in cosmeceutical industry.

QUALITATIVE METHODS

Qualitative methods include focus-group discussions and in-context interviews. Focus group discussions typically involve a small group of people brought together and asked to discuss certain topic. Focus group discussions help in identifying market trends. In-context interviews are conducted when a service is being performed or while using a product. In context interviews provide insight into favourable

product attributes. Analysis of data from qualitative techniques can be tricky. For example it is difficult to assess whether the clients give more importance to the cost or the effect of a service or product. Statistical techniques like conjoint analysis can be used to determine how clients prioritize product or service attributes. For conjoint analysis a set of potential products or services is shown to clients. Clients are asked to arrange the set in the order of their preference. The importance of each factor can be computed from the responses by conjoint analysis.

QUANTITATIVE METHODS

Examples for quantitative tests include blind tests and usage tests. In blind test the participants are asked compare two products without revealing the brand. In usage test the participants are aware of the brand and the concept before they use the cosmeceutical. The number of participants is large and the quantitative data can be analysed using statistical tests and the results are representative of the total target population. Electronic medical records (EMR) and billing software also provide pertinent quantitative data important for assessing the long term performance of a product or service.(22)

Conclusion:

Research in cosmetic dermatology makes use of the same tools and principles of pharmaceutical research though the application may be

different. Research team in cosmetic dermatology has to liaise effectively with the decision makers and the marketing team.

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Figure 1. A typical influence diagram

