

The Therapeutic Ladder - A Clinician and a Patient Perspective

Keywords: Therapeutic Ladder; Therapeutic choices; Acne Vulgaris; Erectile Dysfunction; Benign Prostatic Hyperplasia Prescription cost; Socialized health care; Health care provider; The World Health Organization; Social economic and demographic factors; Millennial Patient pathway; Dermatology; Urology; Quality of Life; Mental health; Suicide; Lower urinary tract symptoms; Urinary retention; Renal Insufficiency

Abstract

Introduction: The therapeutic ladder has been well described in literature by many organizations over many years but rarely is the point of entry and the number of steps for the patient examined. It is reported anecdotally that the millennial would rather have a shortened therapeutic ladder.

Materials and Methods: A review of therapeutic ladders across the disease areas of pain management, acne vulgaris, Erectile Dysfunction and benign prostatic hyperplasia and original research of a qualitative phone interview of 24 dermatologists in the UK and Germany.

Results: A shortened therapeutic ladder will create benefits for the patient who wants to return to normal daily activity as soon as possible disease free and it will help in their mental health and quality of life at the same time potentially saving healthcare costs in both time and treatments and probably help the wider economy.

Conclusion: Further research is needed into the wider healthcare economics of changing the way we address the therapeutic ladder. Shortening the patient pathway may give great benefits to the healthcare systems, healthcare funders, the wider economy and the patients overall long-term health outcomes.

Introduction

The therapeutic ladder has been well described in literature by many organizations over many years but rarely is the point of entry and the number of steps for the patient examined and often at each step the patient has a cost and a visit to a health care professional incurring a cost in time and money and potentially a prescription cost [1]. In socialized health care settings there is also a cost to the health care provider.

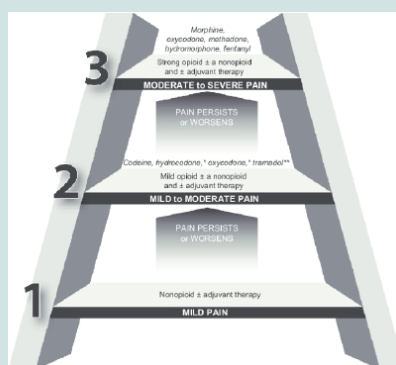


Figure 1: The World Health Organization pain ladder bases therapeutic choices on pain intensity and makes no provision of neuropathic or mixed pain syndromes. Notes: *In fixed-dose combination products, such as oxycodone and paracetamol or hydrocodone and paracetamol. Adapted from world Health Organization pain ladder. 127.



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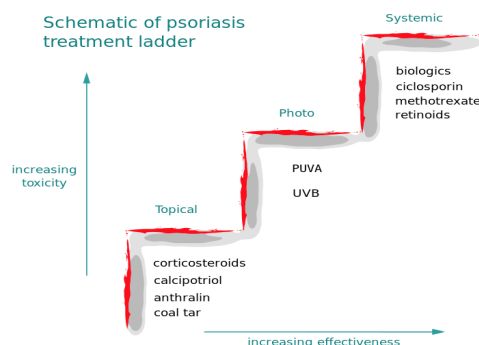
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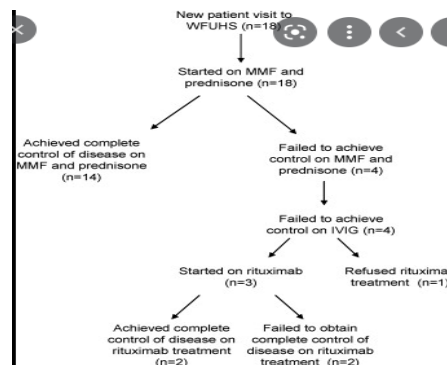
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Therefore it is important that the entry point of the patient is examined in the clinical treatment pathway as well as the patient's expectations and potential outcomes. It is interesting to note that patient entry points may depend upon outside social economic and demographic factors [2].



It is reported anecdotally that the millennial would rather enter the therapeutic ladder and have a treatment with a high degree of efficacy and effectiveness despite increased severity of treatment than follow the steps up the ladder.

Often the patient pathway map or therapeutic ladder has 'failed to achieve' and so to the next step or the patient can step off the ladder at any step as they are asymptomatic at that point [3].



For the health care provider the rational behind the therapeutic ladder and decision making pathway has often been that if the first line treatment is efficacious and effective in a % of patients that percentage will not go on to require the next step and so on reserving the most effective but often aggressive and therefore often more expensive treatment for the most severely affected patients.

The question is if this is fair and equitable to the patient with the disease ?

As more and more treatments are available OTC – Over The Counter often times patients have tried a wide variety of treatment options prior to attending a health care professional and with the internet, along with being well informed are often ill informed and have tried a wide variety of ‘alternative’ and often un-regulated treatments so the patients therapeutic ladder or pathway is often already tall and steep prior to accessing primary or secondary healthcare.

The World Health Organization describe the analgesic ladder as “A framework for treatment ...”[4].

We can look at a therapeutic ladder for any disease or dis-ease across any area or speciality, acute or non-acute, and map the journey of the patient as they navigate the healthcare system and the number of touch points with healthcare professionals. In dermatology the therapeutic ladder usually starts with a topical therapy and then proceeds to a systemic therapy [5].

However the patients therapeutic ladder may well have started with a topical therapy or more than one OTC, Over The Counter preparations. Generally speaking, one considers using a systemic therapy for the management of a dermatological disorder when a disease entity confined to the skin fails to respond to topical therapy, topical therapy is not tolerated by the patient or is impractical given the extent of cutaneous involvement, the skin disease has associated internal organ involvement that cannot be treated with topical therapy alone, or the skin disease alone may potentially lead to significant morbidity and / or mortality if left untreated [6-10]. Little mention is made directly or indirectly in published literature to the patient preference for Quality of Life reasons to escalating treatment choices up the ladder to a more efficacious treatment option. Also there is little discussion made of the mental health issues caused to a patient by a disease but not directly related to the disease[11-16].

In the case of Acne, we know Acne is associated with depression and anxiety. Suicide is positively associated with acne and Acne may significantly increase suicide risk. However, the relationship between acne and suicide is still unclear [17-18]. Acne can affect facial

appearance and lead to mental health problems, such as depression, anxiety and suicide [19-24]. One study results showed that acne was positively associated with suicide. Some previous literature has also indicated that acne is associated with major depression and suicide [25,26]. In addition, the study by Halvorsen and colleagues revealed that acne is associated with social and psychological problems [27]. Adverse events, including suicidal ideation and depression, which have been associated with therapies for acne, may reflect the burden of substantial acne rather than the effects of medication. In America, the suicide rate is 10.8 per 100,000 persons, and suicide is the 11th leading cause of death, accounting for 1.4% of all US deaths. In total, 9%–15% of US dermatology patients with psoriasis, atopic dermatitis, and acne are at risk of suicide. In summary, a meta-analysis demonstrates that acne may significantly increase suicide risk. Clinicians should actively treat acne and consider suicide screening. Further international studies with high-quality analyses are needed as more data is published [28].

It therefore stands to reason that the patient is treated as efficaciously as possible and in the shortest time frame as the risk of adverse mental health over and directly related to their condition continues and increases over time especially if repeating treatments that are not providing clinical or perceptive improvement. This is the same for all conditions.

We chose to look at 3 potential therapeutic ladders for 3 different and disparate diseases affecting different percentages of the population but predominately in the male population

- Acne
- Erectile Dysfunction
- Benign Prostatic Hyperplasia

Acne is estimated to affect 9.4% of the global population, making it the eighth most prevalent disease worldwide. Epidemiological studies have demonstrated that acne is most common in post pubescent teens, with boys most frequently affected particularly with more severe forms of the disease [29]. Acne Affects between 40 million and 50 million individuals in the United States. Although acne mainly affects adolescents, it is also present in children and adults. One study found some degree of facial acne in 54% of women and 40% of men older than 25 years [30-35]. Erectile dysfunction (ED) represents an increasing health concern causing significant impact on the quality of life (QoL) of men globally. It is estimated that 322 million men worldwide will be affected by ED by 2025, an increase from 152 million men in 1995 [36]. Erectile dysfunction is a common medical problem affecting approximately 15% of men each year [37-40]. Severe erectile dysfunction is an independent predictor of poor quality of life and not an indicator for comorbid diseases [41-46]. Erectile dysfunction may have a physiological or psychological basis, but the most common cause is thought to be related to vascular abnormalities of the penile blood supply and erectile tissue often associated with cardiovascular diseases and their risk factors [47-50]. The prevalence of erectile dysfunction varies widely in studies from different countries. It was estimated to be 18.4% in men aged ≥ 20 years in the United States [51], 49.4% in Canada [52] and 63.6% in Hong Kong [53]. In a study in Qatar the prevalence

Table 1: When to consider initiating systemic therapy or moving up on a therapeutic ladder.

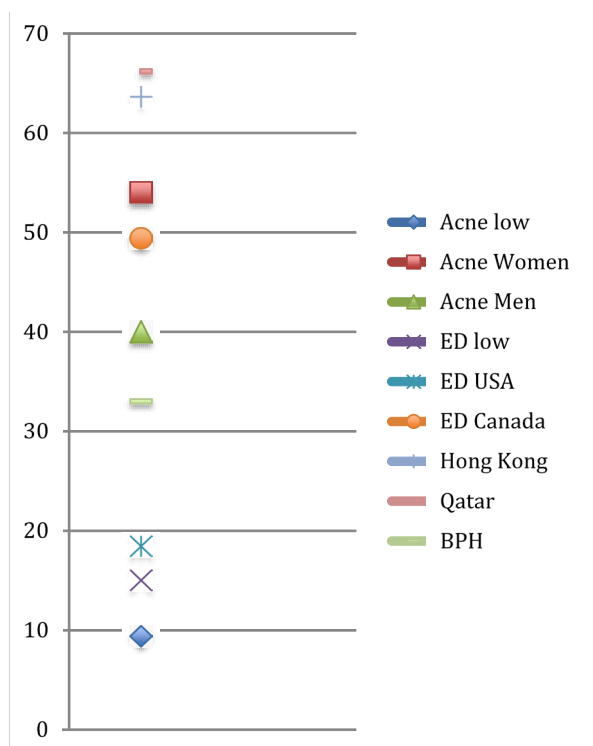
Topical therapies are not available, impractical for the given amount of cutaneous disease or are ineffective in controlling disease
Disease is reversible or controllable.
A Clinical; response to therapy can be measured
The disease being treated is of substantial health risk to the patient If effective treatment is not started (i.e., the skin disease has associated internal organ involvement, is serious, or is life threatening)
The least potentially toxic effective systemic therapy has been tried and failed

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of erectile dysfunction among Qatari patients was 66.2% among hypertensive patients and 23.8% among non-hypertensive controls [54,55]. Benign Prostatic Hyperplasia BPH is a common problem that affects the quality of life in approximately one third of men older than 50 years. BPH is histologically evident in up to 90% of men by age 85 years. As many as 14 million men in the United States have symptoms of BPH. Worldwide, approximately 30 million men have symptoms related to BPH [56]. Benign prostatic hyperplasia (BPH) is one of the most common urological diseases among men [57]. It is characterised by a benign overgrowth of prostatic tissue around the urethra, which ultimately constricts the urethral opening, resulting in lower urinary tract symptoms (LUTS). Symptoms associated with LUTS include urgency, frequency, nocturia, incomplete urination, and weak urinary stream [58]. If left untreated, complications such as urinary retention, renal insufficiency and bladder stone can occur, requiring surgical intervention. BPH has also been associated with other medical morbidities, such as increased risk of falls [59], reduced quality of life [60] as well as increased annual healthcare cost [61,62].

Together we can see that each of the 3 disease areas we have chosen to look at affect significant percentages of the population and significantly reduce quality of life.

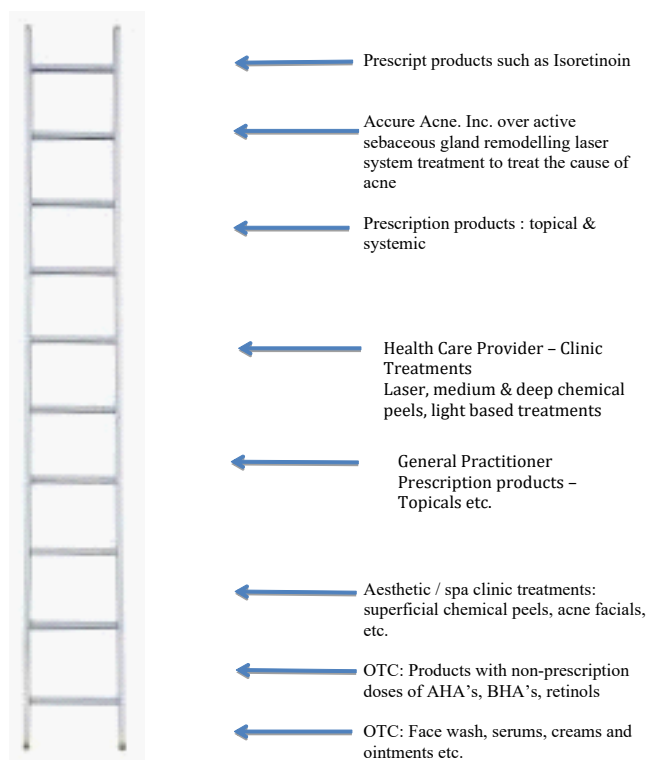
Percentage %



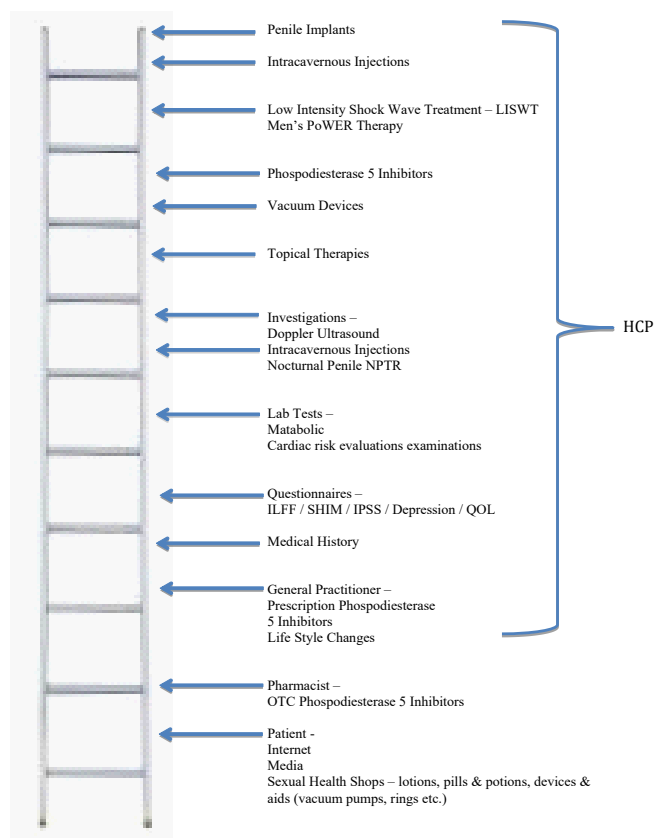
The 3 dis-ease areas we have chosen to look at also affect a wide range of adults, 18 + if we look at the therapeutic ladders for each disease we will see that there are many steps both over the counter, self medication / treatment and directed by health care professionals / health care providers.

The Therapeutic Ladder or patient journey map

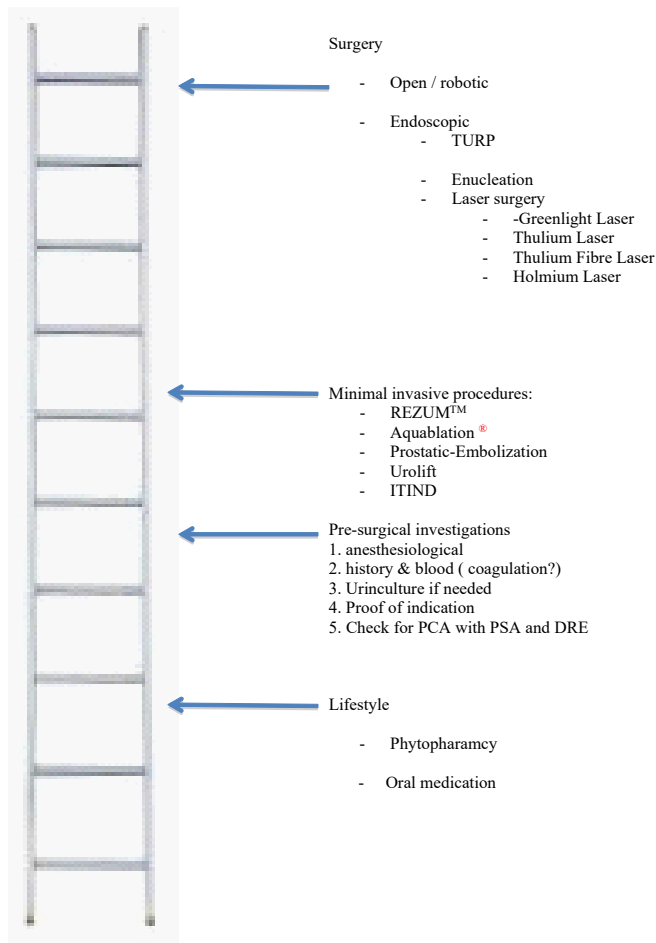
1. Acne



2. Erectile Dysfunction



3. Benign Prostatic Hyperplasia



Symptoms leading to immediate surgery:

- Urinary stasis kidney
- Bladder stone
- Recurrent
- Urinary infection
- Urinary retention
- Prostatic bleeding

Symptoms leading to individual, Step Wise therapy

Urge, nocturia, dribbling, latency, high residual volume

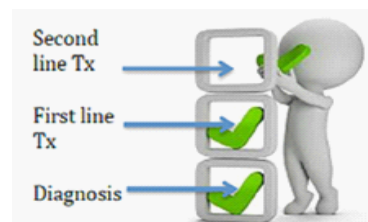
A discussion around shortening the therapeutic ladder for the patient as well as the health care provider and healthcare funder should possibly take place as each step incurs a cost to all parties concerned [63-66]. It is reported anecdotally that the millennial would rather enter the therapeutic ladder and have a treatment with a high degree of efficacy and effectiveness despite increased severity of treatment rather than follow the steps up the ladder. One issue reported and found in the original research conducted was that medications could not work fast enough for patients facing social pressures. "Patients want faster response rates [67]. They see a 50% improvement in six

months time. They want significant improvement in one month". Therefore it stands to reason that any opportunity to show faster results would provide significant leverage with patients, healthcare providers and healthcare funders [68-70].

In the case of Acne, from the original research, patients appear less satisfied than dermatologists with the duration of treatment [71-73]. Research also showed patients want timely treatment for painful or / and embarrassing conditions. They don't want to have to fail a string of medications / treatments before getting what they want or need and require [74-76]. Therefore what patients want is a shortened therapeutic ladder.

One research candidate described

"The number of treatments they have to go through is not cost effective. They're spending thousands on managing relapses and maintenance [77-81]. They suffer psychological stress because they can't afford it. They end up trying to get treated on compassionate grounds [82-85]. The NHS won't offer the treatment they want and the instant fix they're looking for [86]. There is quite high demand, they didn't understand the expense up front" [87]. There is definite demand for a shortened therapeutic ladder by patients with fewer steps, less chance of relapse and an overall faster time to being asymptomatic and the relief of symptoms, which will alleviate the social and mental health pressures as well as the effects and physical disabilities of disease [88-94].



Discussion

Patients, Clinicians. Healthcare Providers and funders want a shortened therapeutic ladder or stepwise therapy which will save healthcare costs in both time and treatments and be beneficial to the patient and probably help the wider economy with a healthier population [95-100].

Further research is needed into the wider healthcare economics of changing the way we address the therapeutic ladder [101-111].

Conclusion

Further research is needed into the wider healthcare economics of changing the way we address the therapeutic ladder.

Shortening the patient pathway may give great benefits to healthcare systems especially as these systems and providers are under greater pressure to treat more patients with fewer resources, so therefore shortening the therapeutic ladder to fewer steps, so therefore patient visits and interactions, may free up valuable resources that are in short supply whilst giving the patient the most efficacious treatment first time, every time.

Healthcare funders may also benefit from cost savings in visits and tried and failed therapies by adopting a shorter therapeutic ladder

and moving to the state of the art and the most efficacious treatment with a higher percentage success rate in a shortened patient pathway.

The wider economy could also benefit with greater taxation, both direct and in-direct and lower costs in a socialised healthcare system, from a healthier population, quicker, through the adoption of a short therapeutic ladder

Anecdotally the millennial would rather enter the therapeutic ladder and have a treatment with a high degree of efficacy and effectiveness despite increased severity of treatment.

We must not forget that patients see each visit, even for diagnostic tests and check-ups as a procedural visit to the healthcare provider and so if one adds up all the steps of the therapeutic ladder for a specific patient and adds all the visits for diagnostic tests, pre-theatre workup and check-ups the number of visit and consultations can be quite high. Increasingly in areas such as oncology the number of visits is being reduced with a back-to-back, same visit, service and this can be extended to all areas of healthcare.

Patients overall short term and long-term health outcomes would be improved by a shortened therapeutic ladder and short treatment cycle, fewer prescription charges along with improvements to their quality of life and mental health.

With further healthcare economics and Value Based Health Care research a shortened therapeutic ladder can be validated for efficiency for the healthcare provider, healthcare funder and the patient.

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