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Review Article

GUIDELINES IN CLINICAL PRACTICE : A DICTUM OR A DAMN..?!

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Abstract :

Clinical practice guidelines are systematically developed statements that assist practitioners to provide appropriate evidence-based care. They are often created by statutory bodies, expert associational advisory committees, government and regional offices and even individual hospital policy groups. The objectives of clinical guidelines are to standardize medical care, to raise the quality of care and to reduce several kinds of risks to the patient and health care provider. Implementation of clinical practice guidelines is a complex process and protocols with good quality, with clinical importance and prioritization of topics, and a user-friendly format are usually successful. In day to day clinical practice guidelines are not strictly followed. The merits and demerits of guideline based practice patterns have been analyzed here. There could be many reasons for the non adherence to protocol based medical practice which has to be addressed. A historical perspective of guidelines and a breach in standardized practice is also mentioned. As there can be fallacies in protocols; a clinical practice that is not strictly adhering with guidelines, should not be considered as a wrongful treatment strategy.

Keywords : Guidelines, protocol, clinical practice, adherence

Introduction :

As long as each human being is unique, the illness affecting his system should also be 'unique'. The aberration of the bodily mechanisms are labeled as symptoms, signs and diagnoses in medical text books by the collective wisdom of our predecessors who have compiled as much information about most abnormal human situations. Generally, in clinical practice we try to ascribe an individual's problem to one of the described or classified areas of medical knowledge and try suggesting a solution. We practice medicine with the ideas imbibed from books, teachers and our own past experience. It's a spontaneous act which gets moulded or remodelled regularly. Every one of us have witnessed many unexpected turn of events in clinical practice which we fail to explain with our existing basis of knowledge, probably because of an un-identical nature of the human system; hence we end up saying 'diseases will not read text-books!'. If this is the scenario in common medical practice, how can we generalize disease related events into particular guidelines?

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Even in this era of evidence based medicine; the relevance of an age old query “Is medical practice just a science or is there a need to add a pinch of 'art' for its fruitfulness?” still exists.

The dramatic events that happened to an octogenarian suffering from carcinoma prostate is an example of application of protocol based practice in real life. He was deferred radical prostatectomy by a consultant, who felt the patient age to be above the upper limit according to the guidelines for a radical surgery, obtained by feeding the data into software. This data was analyzed and calculated by using prostate cancer prediction tool from Memorial Sloan Kettering Cancer Centre (MSKCC)[1,2]. The MSKCC prostate cancer prediction tool was based on Kattans nomogram to know the organ confined status of the prostate carcinoma and to assess the recurrence free survival after a radical prostatectomy[3]. Interestingly, the same patient later underwent radical prostatectomy by another consultant who holistically approached the problem and is now enjoying a fine tuned life. Even though

the decision for radical surgery in this instance did not adhere to the current guidelines, it can be strongly argued by quoting CaPSURE[4] and other studies which show that the validation of Kattans nomogram, as 'may not be accurate in all clinical scenarios' especially with different ethnic groups and non-institutionalized patients[5,6,7].

Why do we need guidelines?

Guidelines are designed for uniformity and to provide an overall better and improved patient outcome. Proper protocols will standardize the pathways; hence a discretionary subjective handling of a delicate event can be withheld. Guidelines are often created by statutory bodies, expert associational advisory committees, government and regional offices and even individual hospital policy groups. It is based on the most prevalent, more suitable and an acceptable directional lead in a particular clinical event. It's a planned journey; so the time, energy, expenditure and the workforce used would be definitely less and one would reach the 'target' promptly. Without guidelines, it is akin to one losing the path in a dense forest and not reaching the destination.

If a hospital is following a particular guideline in a disease condition, the final result can be achieved without much expert supervision. Suppose a patient is admitted to intensive care unit, he will be treated according to the fluid management protocol, antibiotic protocol, ventilation guidelines and blood investigation protocols. The team involved will follow the guidelines religiously and as a result reducing the need for availability of a round the clock bedside consultant, without adversely affecting the final outcome. Another classical example in Urology to support this opinion is with regard to the procedure of Intravenous Urography (IVU). Ideally this is an expert supervised imaging, who plans and times the next x-ray shoot seeing the earlier film and brings out the most relevant information in the urinary tract. In current practice, IVU's are done by technicians simply following the guidelines prevalent in their radiology suite, without an expert radiologist or urologist in the room. Still they are able to provide the best information about the urinary system.

Another advantage in following guidelines is avoidance of irrational treatment. It brings uniformity in patient care and even reduces the cost of treatment. If a hospital has a strict antibiotic policy, whether in treating urinary tract infection or prophylactic antibiotic administration for an elective surgical procedure, it avoids inconsistent prescriptions, lowers the treatment cost[8,9] and most importantly resists the emergence of newer vigor strains in clinical practice[10,11].

I will not cut for stone.....

The history of 'Good Clinical Practice' statute traces back to one of the oldest enduring traditions in the history of medicine – 'The Hippocratic Oath'. As the guiding ethical code, it is primarily known for its edict to do no harm to the patient. The practice of medicine starts by bowing to the Hippocratic Oath. The breach of guidelines in clinical practice dates back many centuries. The existence of a true urology specialty would not have happened if this violation of guidelines in recommended practice had not been done in the past.

The original version of this oath clearly depicts that the physician should not surgically treat Calculus disease[12] (I will not cut for stone even for patients in whom the disease is manifest). Greek tradition was against opening the body, and the Hippocratic Oath warns physicians against the practice of surgery. “I will not cut persons laboring under the stone, but will leave this to be done by men who are practitioners of this work”. The people who dared to treat the stone disease by violating the norms were neither rewarded nor incorporated into the aristocratic family of physicians. The act was relegated to barbers who did not have basic education. We surgeons should pay our tribute to those chirurgeons of the 5th century B C, whose daring act saved a lot of lives and stimulated the subsequent generations to emulate a proper practice of surgery.

Even in the earlier medical practice before Hippocratic era, violation of guidelines in surgical practice was noted. The first civilization in Mesopotamia had rules governing the practice of medicine mentioned in their earliest law code dating back to 1750 B C[13]. To bring about the rule of

righteousness in the land, the king Hammurabi encoded many laws for the well being of mankind in ancient Babylon[14]. The Sumerians at that time realized that uniformity in clinical practice was not an achievable target, and strict laws were implemented to physicians to avoid alteration in treatment patterns.

Non adherence to guidelines

In most of the situations the treating physicians are not familiar with the current guidelines applicable to the problems they are dealing with. The reasons could be the lack of updated knowledge in the field due to poor reading habits, lack of attendance in continuing medical education (CME) programs and conferences, poor interaction with colleagues and finally not utilizing the newer age technologies. The effort from central and state medical councils to provide credit hours for strict attendance in CME's and renewal of medical council registration are new approaches to tackle this situation.

Some doctors hold a different view about guidelines 'that they are not definitions and it's only a signboard to reach the destination'. There are too many guidelines in a clinical scenario and they are inconsistent too. There are frequent changes in guidelines to an extent as if the treatment offered for the same condition in the past was incorrect.

Sometimes if you need to strictly follow the guidelines you end up in conducting additional investigations which has its demerits too, such as non-availability of those facilities in a particular hospital or a town resulting in patient inconvenience. Further, these additional tests will escalate the cost involved in treatment.

Many physicians feel that clinical practice is a spontaneous act and the decisions taken are in the best interests of the patient. No two physicians will think exactly in the same pattern in a particular clinical event though their decisions may be closely similar. The time and effort taken to place the particular clinical event into one of the guidelines outlined for those situations are little prolonged and not suitable for routine medical practice. So they believe that guidelines are meant for clinical trials, disease studies and for institutional practices only.

Analysis of guidelines based clinical practice

The debate on management options for a proximal ureteric calculus is still continuing. The literature base for the 1997 American Urology Association (AUA) guidelines indicated that for proximal ureteral stones of <1 cm size, ureteroscopy (URS) provided a median success rate of only 56%, while shock wave lithotripsy (SWL) was the preferred treatment modality with a stone free rate of 84%[15,18]. By contrast, the 2007 AUA-European Association of Urology (EAU) Ureteral Stone Guideline panel highlighted the advances in URS in the previous decade and reported that the stone-free with SWL and URS for small <1 cm proximal ureteral stones were 90% and 80% respectively [16,18].

Even with guidelines showing a better result with SWL, the use of endourological stone procedure is commonly perceived to be on the rise. Most urologists would agree that many facets of physician preference affect the choice of treatment modality for a given case. The study by Matlaga[17] showed that urologists in the initial certification cohort preferred URS in 52% cases; whereas more senior urologists performed ESWL in up to 60.5% cases. The possible explanation for this trend could be dramatic advance in endoscopic technology compared to SWL technology and the fact that young urologists are now introduced to state-of-the-art endoscopic technique during their training at academic centers. In addition, some senior urologist might be less likely to be exposed to technical innovations or are reluctant to devote time to learning newer, more advanced technologies (Lingeman[18]).

Another factor that might affect the choice of treatment is the financial incentives involved in preferential selection of procedure. Also younger urologist prefer the more technically challenging endourological methods with their more certain outcomes and keep SWL as a secondary option[18].

Practice patterns in the choice of treatment modality are also affected by factors such as access to facilities and the proficiency and preference of individual urologist. Even

though we know the fact that success rate of SWL is significantly better with shock waves at rate of 60/minute or slower, incorporating a brief pause after the initiation of treatment (protects against renal injury) and with low to moderate acoustic pressures [18], these guidelines are practically not followed as most SWL technicians are mandated to follow a set protocol specified by their institution or service. The situation is worsened if it's a high volume stone centre as it is required to finish 'more cases' a day [18].

Arguably, the best treatment for a proximal ureteral calculi will be administered in a setting in which the urologist has the freedom to determine and adopt strategies that are objectively proven to improve outcomes and minimize adverse effects [18].

Fallacies in guidelines

Guidelines are available from various professional societies for the evaluation and use of testosterone replacement therapy in hypogonadal men. The guidelines proposed by American Association of Clinical Endocrinologists (AACE) and by the Endocrine Society differ with respect to the proposed lower threshold for serum testosterone with cut off values as 7nmol/L (200ng/dl) and 10.4nmol (300ng/dl) respectively. See Table 1 [19,20,21]

Table 1: Biochemical definitions of hypogonadism [22].

Guidelines	nmol/l	ng/dl
EAA, ISA, ISSAM, EAU, ASA	Mild <12	<340
	Severe <8	<231
Endocrine Society	<10.4	<300
AACE	<7	<200

With different definitions in place, the prevalence of hypogonadism varies a lot. Mean while, the European Academy of Andrology (EAA), the American Society of Andrology (ASA), the European Association of Urology (EAU), the International Society of Andrology (ISA) and International Society for Study of Aging Male (ISSAM) feel that guideline should define hypogonadism as mild (<12nmol/1) and severe (<8nmol/l).

With seven societies in place and each with a different definition; the physician and the patient at the receiving end will feel confused to follow any of the guidelines and will either depend on the laboratory value for the range of normalcy or go back to his old textbooks. These societies through have shown a general agreement or consensus that a patient can be treated for hypogonadism if there is presence of hypogonadism related symptoms, low sexual desire or erectile dysfunction.

Conclusion

Clinical practice guidelines are systematically developed statements that assist practitioners to provide appropriate evidence-based care. The objectives of clinical guidelines are to standardize medical care, to raise the quality of care, to reduce several kinds of risks (to the patient, the healthcare provider, medical insurers and health plans) and to achieve the best balance between cost and medical parameters such as effectiveness, specificity, sensitivity and resoluteness. Implementation of clinical practice guidelines is a complex process. The three crucial elements of successful guidelines are good quality, clinical importance with prioritization of topics, and a user-friendly format. A humane and holistic approach should be added to the science of clinical practice. As there can be fallacies in protocols, a strict non-adherence to guidelines should not be considered as a wrongful treatment strategy; rather a medical practice which is either close to or parallel to the guidelines mentioned should be taken as an appreciable treatment policy.

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