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Overstating Conclusions from Population-Based Data:
Be Careful What You Wish For!

New data is always welcome, provided the information was captured accurately and the results analyzed and interpreted properly. However, how that data is incorporated into the management of individual patients requires thoughtful consideration by the clinician caring for that patient. The relationship between the physician and their patient requires a special respect when considering how care is managed and how treatment is selected. Of course, it is important for the clinician to be as well informed and current as possible on both the history and examination of the patient and the scientific information about the treatment and monitoring of the patient's medical condition. Nevertheless, at the end of the day, the physician must be dedicated to what they believe is in the patient's best interest and ultimately is responsible both medically and legally for the decisions made in caring for the patient.

Two recent articles have addressed data regarding laboratory monitoring when utilizing two specific oral agents, spironolactone and isotretinoin, in the management of acne vulgaris (AV). The first on spironolactone addresses whether or not baseline measurement of the serum potassium level is needed when treating healthy adult women with AV. In an analysis from 974 healthy adult women with AV who had no risk factors for predisposition to hyperkalemia, 13 abnormal serum potassium values were identified among a total of 1802 measurements, with 6 of the 13 normalizing with repeat testing.[1] The data analysis from this study population showed that the rate of hyperkalemia in healthy young women taking spironolactone (0.72%) for AV is equivalent to the baseline rate of hyperkalemia (0.76%). The authors concluded that routine potassium monitoring is unnecessary for healthy women taking spironolactone for AV. The second article reported results from a meta-analysis of 26 studies examining laboratory monitoring results in patients treated with isotretinoin ≥40 mg/day for at least 4 weeks.[2] Results showed that a significant change in mean values of several laboratory tests (WBC count, hepatic and lipid panels) occur, mean changes across the patient group did not meet criteria for high-risk, and the proportion of patients with laboratory abnormalities was low. In addition, abnormal laboratory results were most likely to be identified within the first 2 months of starting isotretinoin therapy. It was concluded that the evidence from this study does not support monthly laboratory testing for use of standard doses of oral isotretinoin for the standard patient with acne.

First let me emphasize that data from studies, such as the two discussed above, is always welcome. However, how the conclusions of a study are interpreted and utilized is an area of major concern. The results from these studies should not be a surprise to any dermatologist who has any reasonable experience with prescribing spironolactone and/or isotretinoin. *However, the reason for laboratory monitoring ordered by a physician for an individual patient is not based on what happens within a large population.* That population is not in the room with the physician, however, the individual patient is. *The reason for laboratory monitoring is to detect the outlier, as drug-related side effects that may be clinically significant yet uncommon are under the umbrella of what the physician is monitoring the patient for.* It is not prudent to say that the monitoring "is unnecessary". It is reasonable to say that it "may be unnecessary". Ultimately, judgment and decisions need to be left with the physician and their patient. Reporting data is a great thing. Hats off to my colleagues for putting in the time and effort to collect and report the information. However, how it is interpreted and incorporated may not be such a great thing depending on how the information is utilized. Being too dogmatic with recommendations from the data is too restrictive, and is not a reasonable approach.

We must remain practical and not open the door for medical practice to become an algorithmic and robotic endeavor devoid of individual clinical judgement. Neither the clinician nor the patient who is an outlier wants a clinically relevant laboratory abnormality to remain undetected. Being too dogmatic with results from such studies is especially of concern if third-party payers use the information to deny or complicate coverage for certain laboratory tests based on the population data.

I am honored once again to serve as Guest Editor of this Acne and Rosacea issue for the *Journal of Drugs in Dermatology*. I hope you found this guest editorial to be enlightening and the issue to be helpful in expanding your knowledge about acne and rosacea.

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References

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2. Lee YH, Scharnitz TP, Muscat J, et al. Laboratory monitoring during isotretinoin therapy for acne: a systematic review and meta-analysis. *JAMA Dermatol.* 2016;152(1):35-44.