

tolvaptan 用於延緩多囊腎腎功能的惡化

209 期腎友週報(107 年 2 月 21 日)曾介紹用於延緩多囊腎 (ADPKD) 患者腎功能惡化的藥物 tolvaptan，美國食品藥物管理局(FDA)也在今年 4 月 23 日核准 tolvaptan 使用於符合條件的多囊腎病患。2018 年 10 月 J Am Soc Nephrol 期刊刊出一篇報告簡介美國建議的 tolvaptan 使用條件、排外條件、利弊得失、須注意的副作用及必須停藥的時機。該報告根據 Mayo classification 將多囊腎病患依年齡(age)及經過身高校正的腎臟體積(HtTKV)區分為 class 1A, 1B, 1C, 1D, 1E 五組，其中 class 1C, 1D, 1E 病患的腎功能惡化的速度較快，為每年衰退 2.36 至 4.78(ml/min/SA per year)，這三群病患才符合使用 tolvaptan 的條件。(Figure 3)

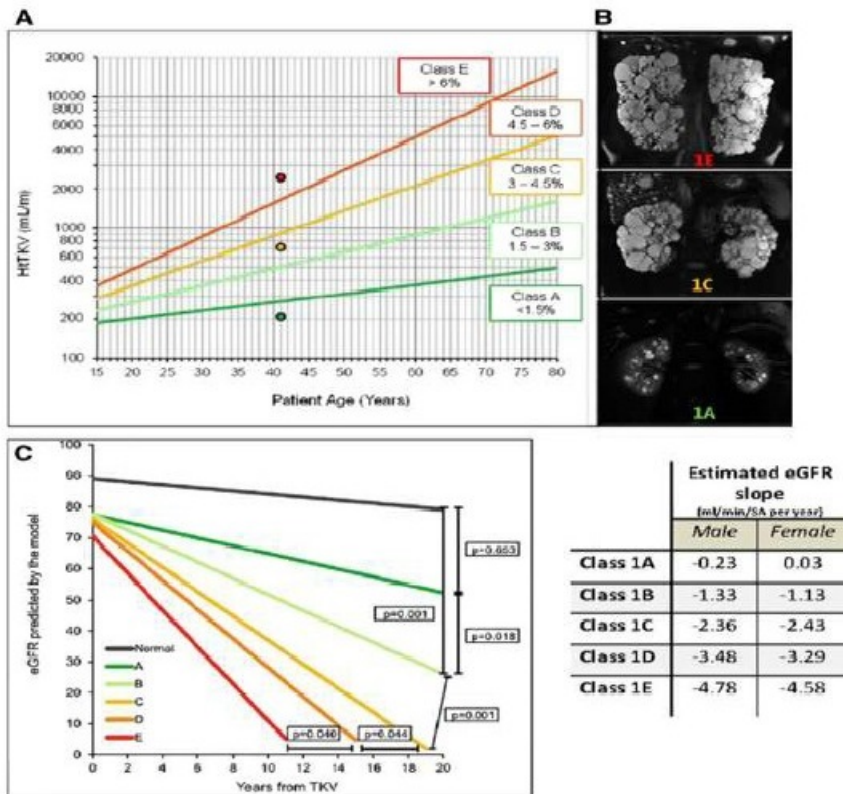


Figure 3. The Mayo imaging classification provides a simple tool for the identification of

不同於 209 期腎友週報內容介紹歐洲腎臟醫學界建議的治療決策流程，美國提出的治療決策流程是以上述 class 1C, 1D, 1E 病患作為治療對象。(Figure 4)

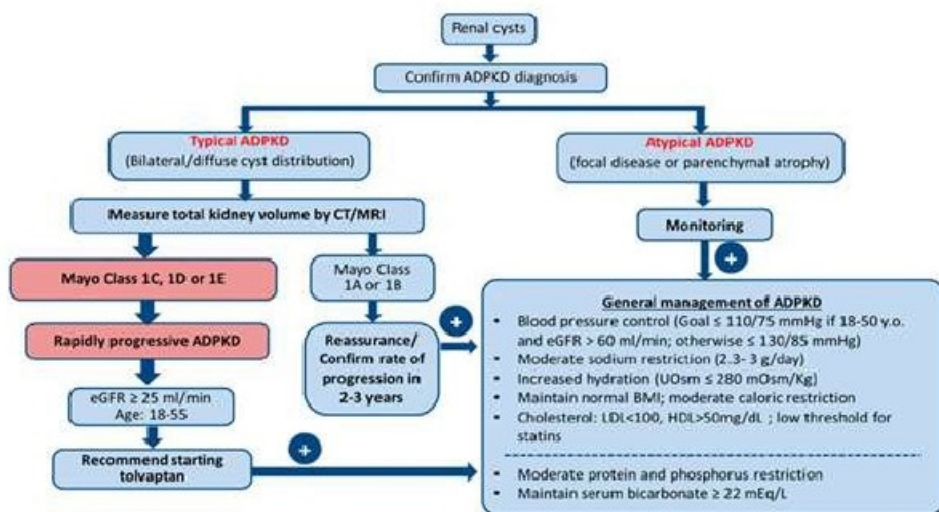


Figure 4. The algorithm depicted in the Figure summarizes a practical approach to identify the patients more likely to benefit from

tolvaptan 延緩多囊腎腎功能衰退的效果用 Figure 5 表示：藍色線是使用 tolvaptan，紅色線是未使用 tolvaptan，可以看出 tolvaptan 對於不同腎功能狀況的病患均具有延緩腎功能衰退的效果，它可以延緩進入洗腎的年數為 1.5~7.3 年，這種效果在腎功能相對較佳的多囊腎病患更明顯。

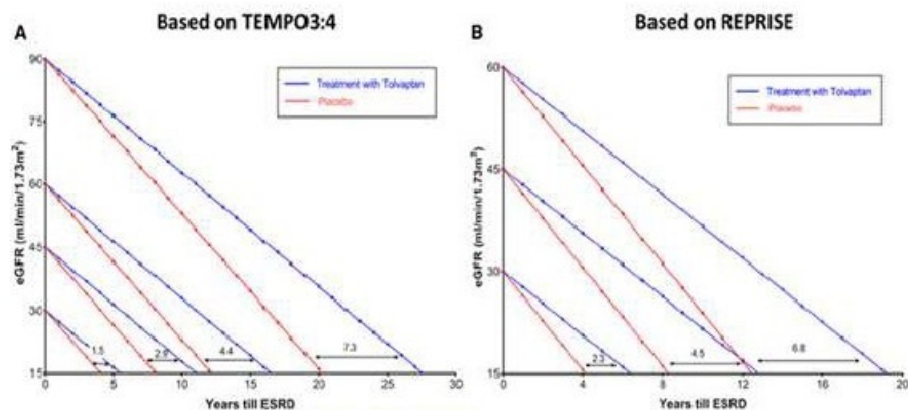


Figure 5. Extrapolations from the results of the TEMPO 3:4 and REPRISE trials allow estimations of the potential benefit of tolvaptan treatment in

凡是藥物都有副作用，tolvaptan 最嚴重的副作用是肝臟毒性，一旦發現就要立

即停藥，以避免造成不可逆的肝衰竭。(Table 4)

Table 4. Potential benefits and harms from tolvaptan treatment in ADPKD

Benefits	Harms
Slows kidney growth	Polyuria, pollakiuria, and nocturia
Slows eGFR decline	Thirst and fatigue
May delay need for renal replacement	Uric acid elevations (rarely gout)
Reduces pain, hematuria, stone, and urinary tract infection events	Transaminase elevations and risk of severe hepatocellular toxicity
Slight reduction in BP	Need for frequent monitoring of liver function
	Possible drug interaction (CYP3A inhibitors)
	Financial burden

由於這個藥物非常貴，台灣是否會核准使用於延緩多囊腎腎功能衰退仍未知，最後附上使用 tolvaptan 須注意事項的兩個流程圖(Figure 6, Figure 7)，若想了解更多，可以跟您的腎臟科醫師詢問討論。

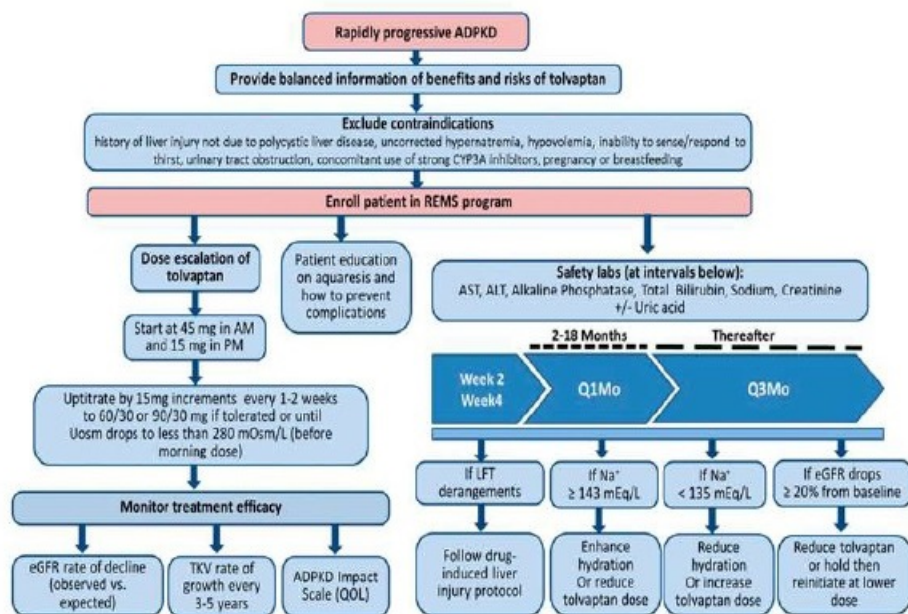


Figure 6. The algorithm depicted in the Figure summarizes the recommended steps for the initiation, titration and optimization of tolvaptan treatment and the schedule of laboratory tests to monitor its safety. LFT, liver function tests; Na^+ , sodium; Q1Mo, every 1 month; Q3Mo, every 3 months.

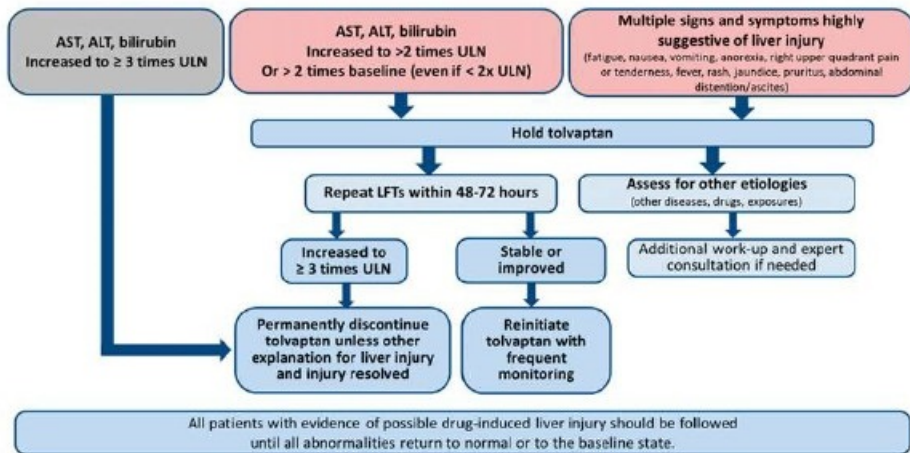


Figure 7. The algorithm depicted in the figure summarizes the recommendations for evaluation and management of potential drug-induced liver injury. LFT, liver function tests.