V Pharm D

Subject: Clinical Pharmacokinetics &Pharmacotherapeutic Drug Monitoring

QUESTION BANK 2016-17

Note: Unit II, IV –Two Chapters are clubbed together

Unit I: Introduction to Clinical pharmacokinetics **No. of Hours: 3**

Short Answers **2 Marks**

1. Give the importance of clinical pharmacokinetics
2. Define apparent volume of distribution and give the mathematical equation to calculate this parameter.
3. Define non-linear pharmacokinetics
4. Describe the difference between first and zero order elimination and how each order appears graphically.
5. Define biological half-life and give it's equation with units.
6. Give the relationship between half-life and elimination rate constant.
7. What is clearance? Give the relationship between clearance, drug dose and AUC.
8. Give the assumptions of compartment model.
9. Define pharmacokinetics. Name and define three pharmacokinetic parameters that describe a typical plasma level time curve.
10. Define loading dose and maintenance dose. Give equations to calculate the same.
11. Give any four applications of clinical pharmacokinetics.

Unit II: (A. Design of Dosage Regimen + Therapeutic Drug Monitoring)

A. Design of dosage regimens **No. of Hours: 7**

Long Answers **10 Marks**

12. Explain the various factors considered in the design of dosage regimen for geriatric and obese patients.

Short Essay **5 Marks**

13. Explain the process and clinical significance of conversion from intravenous to oral dosing.
14. What are nomograms? Explain their applications in pharmacokinetic studies with examples. Give their advantages and disadvantages.
15. Explain in detail the determination of dose and dosing interval of a drug.

16. Describe the principle of superposition and how it applies to multiple drug dosing.
17. Explain the role of nomograms and tabulations in the design of dosage regimen.
18. Explain the different methods of conversion of intravenous to per oral dosing.
19. Explain various factors considered in designing the dosage regimen for geriatric patients.
20. Explain the factors considered in the design of dosage regimen for paediatric patients. Give any two formulae for the calculation of child dose.
21. Explain various factors considered in the design of dosage regimen for obese patients.
22. Why dosage adjustment is necessary in the obese patients. What are the pharmacokinetic parameters to be considered in the dosage adjustment for obese patients?
23. The elimination half-life and V_d of tobramycin was reported to be 2.15 hrs and 33.5% of body weight respectively. What is the dose for an 80 kg individual if a steady state level of 2.5 μg/ml is desired? Assume that the drug is given as iv bolus every 8 hrs.
24. The elimination half-life of an antibiotic is 3 hrs with an apparent volume of distribution equivalent to 20% of bodyweight. The usual therapeutic range of this antibiotic is between 5-15 μg/ml. Calculate the dose and dosing interval that will just maintain the therapeutic concentration.
25. Explain in detail determination of dose and dosing interval of a drug.
26. Enumerate the factors involved in calculation of drug dose in peadiatric patients.
27. Discuss the factors to be considered during the design of dosage regimen.
28. Explain the reasons for converting IV dose to oral dose. Add a note on START and STOP criteria for drugs to be used in patients.

Short Answers **2 Marks**

29. Add a note on START and STOP criteria for drugs to be used in geriatric patients.
30. Write different formulae for calculating child dose.
31. Add a note on BEER's criteria for drugs to be used in geriatric patients.
32. Write the importance of loading dose in finding drug dosing intervals.
33. Give the relationship between elimination half-life and drug dosing intervals
34. Define nomograms and tabulations.
35. Give any two advantages and disadvantages of nomograms.
36. Enumerate the methods for conversion of IV to oral dosing.
37. Give any four factors considered in dosing geriatric patients.
38. What are the factors affecting the drug absorption in geriatric patients?
39. Mention the factors affecting the drug distribution in obese patients.
40. Based on which property of drug, the drug dosage is adjusted in the obese patients and why?
41. Give any four factors considered in dosing obese patients.
42. Mention any four factors considered in dosing paediatric patients.
43. Give any two formulae for the calculation of paediatric dose.
44. Write the formula for the calculation of geriatric dose.
45. What are the factors considered in the conversion of IV to oral dosing?
46. What is the BEER's criteria for drugs to be used in geriatric patients?

B. Therapeutic Drug Monitoring **No. of Hours: 15**

Long Essay **10 marks**

47. Explain the necessity and process of TDM in patients receiving cyclosporine and carbamazepine.
48. List out the indications for TDM. Explain the necessity and process of TDM in patients receiving digoxin and phenytoin.
49. Explain the necessity and process of TDM in patients receiving lithium and methotrexate.
50. Enumerate and explain various factors in individualizing drug dosage regimen.
51. Explain in detail pharmacokinetic/pharmacodynamic correlation in drug therapy.

Short Essay **5 Marks**

52. Explain effect of age and bodyweight in individualization of drug dosage regimen.
53. Explain role of genetics and disease condition in the individualization of drug dosage regimen.
54. Explain role of co-existing diseases and interacting drugs in the individualization of drug dosage regimen.
55. Describe the protocol for TDM of a drug.
56. Define TDM. Discuss the indications for TDM of drugs.
57. Explain the role of clinical pharmacist in TDM.
58. Explain the relationship between dose and pharmacological effect of a drug.
59. Explain the relationship between dose and duration of activity of a drug.
60. Explain with suitable examples how elimination half life of a drug influence the duration of activity.
61. Write about Emax model
62. Explain the sigmoidal Emax model in PK/PD correlation

Short Answers **2 Marks**

63. Enlist various types of samples used for analysis in TDM
64. What do you understand by drug tolerance and physical dependency?
65. Define narrow therapeutic index with suitable examples.
66. Define TDM. Name any four drugs that require TDM.
67. Write the protocol for TDM of a drug.
68. Give any four indications for TDM.
69. Why is TDM necessary for digitoxin.
70. Why is TDM necessary for methotrexate.
71. Explain the necessity of monitoring cyclosporine.
72. Give the necessity for TDM of lithium.
73. Why is TDM necessary for phenytoin.
74. Explain the reasons for monitoring drug levels.

Unit III: Pharmacokinetics of drug interactions **No. of Hours: 5**

Short Essay **5 Marks**

75. Explain the various pharmacokinetic drug interactions with suitable examples*.
76. Explain the influence of drug interaction on drug absorption with examples
77. Discuss drug interactions related to protein binding and metabolism.

78. Describe the role of cytochrome P-450 enzymes in drug interactions. Add a note with suitable examples and their clinical significance.
79. Explain the influence of drug interaction on drug metabolism with respect to enzyme induction and enzyme inhibition.
80. Explain the effect of inhibition of biliary excretion of drugs and list out the drug interactions which influence the biliary excretion.

Unit IV: (A. Dosage adjustment in renal and hepatic disease + B. Pharmacogenetics)

A. Dosage adjustment in renal and hepatic disease No. of Hours: 10

Long Essay 10 Marks

81. Explain in detail the general approaches for dosage adjustment in renal diseases.
82. Explain in detail the different methods of extracorporeal removal of drugs.
83. Discuss various markers used in the measurement of glomerular filtration rate along with their advantages and disadvantages. Enumerate the various formulae used for the measurement of creatinine clearance.
84. Enumerate various causes for renal impairment. Discuss in detail the pharmacokinetic considerations in the renal failure patients.
85. List out various factors for hepatic impairment. Discuss in detail the pharmacokinetic considerations in the hepatic disease patients.

Short Essay5 Marks

86. List various formulae for measurement of glomerular filtration rate.
87. Explain the various pharmacokinetic changes observed in the renally impaired patients.
88. How do you adjust dosage regimen in renal failure patients based on elimination half life of drug?
89. How do you adjust dosage regimen in renal failure patients based on total body clearance of drug?
90. Give the ideal characteristics of a marker to be used in the measurement of GFR.
91. Explain various markers used in the measurement of glomerular filtration rate along with their advantages and disadvantages.
92. Define creatinine clearance. Enumerate various formulae used for the measurement of creatinine clearance.
93. Explain the effect of hepatic disease on pharmacokinetics of drugs.
94. Describe peritoneal dialysis with its advantages and disadvantages.
95. Explain the Giusti-Hayton method for the dosage adjustment in uremic patients.
96. Describe the Wagner method for the dose adjustment in uremic patients.
97. The maintenance dose of gentamicin is 80mg every 6hrs for a patient with normal renal function. Calculate the maintenance dose for a uremic patient with creatinine clearance of 20ml/min. Assume a normal creatinine clearance of 100ml/min.
98. What is the creatinine clearance for a 25 year old male patient with a serum creatinine of 1mg/dL? The patient is 5 ft, 4inches in height and weighs 103 Kg.
99. An adult male patient (52 years old, 75 kg) whose serum creatinine is 2.4 mg/dL is to be given gentamicin sulphate. The usual dose of gentamicin in adult patients with normal renal

function is 1 mg/kg every 8 hours by multiple IV bolus injections. Calculate the appropriate dosage regimen of gentamicin sulfate for this patient.

100. Explain hemodialysis.
101. Explain methods of determining creatinine clearance.
102. Describe the methods of measurement of GFR and their significance.

Short Answers **2 Marks**

103. Enumerate the factors influencing dialyzability of drugs.
104. Enumerate the causes for renal failure
105. Give any four pharmacokinetic parameter changes observed in the renal failure patients.
106. List the markers used in the measurement of GFR.
107. Give any four ideal characteristics of the marker drugs to be used for GFR measurement.
108. Give two advantages and disadvantages of inulin as a marker for GFR measurement.
109. Give the Jellife's equation for the measurement of creatinine clearance.
110. Give the Cockraft and Gault's equation for the measurement of creatinine clearance.
111. Give the formula for the calculation of creatinine clearance in children.
112. Give the MDRD equation for the measurement of creatinine clearance.
113. Name the methods for the extracorporeal removal of drugs.
114. Give any two advantages and disadvantages of peritoneal dialysis.
115. Give any two advantages and disadvantages of haemodialysis.
116. Define intrinsic clearance of drugs with its clinical significance.
117. Calculate creatinine clearance for a 30 year old female patient with a serum creatinine value of 0.8 mg/dl. The patient is 5 ft 1 inch tall and weighs 69 kgs.
118. Name the metabolic markers used in liver function test with their normal values.
119. Define hepatic clearance
120. Give the importance of extra corporeal removal of drugs.
121. Calculate creatinine clearance for a 23 year old male patient with a serum creatinine value of 1.2 mg/dl. The patient is 5 ft 5 inch tall and weighs 98 kgs.
122. Using the method of Cockroft and Gault, Calculate creatinine clearance for a 36 year old female patient with a serum creatinine value of 1.8 mg/dl. The patient is 5 ft 5 inch tall and weighs 58 kgs.

B. Pharmacogenetics **No. of Hours: 5**

Long Essay **10 Marks**

123. Discuss the role and clinical significance of genetic polymorphism in drug transports and drug targets with suitable examples.
124. Discuss the importance of genetic polymorphism of cytochrome P-450 isozymes on drug metabolism with suitable examples.

Short Essay **5 Marks**

125. Describe the role of genetic polymorphism in drug targets.
126. Describe the genetic polymorphism in CYP2D6 and 2C9 isozymes.

Short Answers **2 Marks**

127. Define pharmacogenetics
128. Describe genetic polymorphism in CYP2D6 isozymes
129. Describe genetic polymorphism in CYP2C9 isozymes
130. How do efflux transporters affect the bioavailability of the drugs
131. Give any two examples for clinically important genetic polymorphism of drug targets.
132. Give any two examples for clinically important genetic polymorphism of drug transporters.
133. Describe the role of genetic polymorphism in drug targets.
134. Define pharmacogentics and with suitable examples.
135. With suitable examples, enumerate drug dosing in genetic dependent fast acetylators.

Unit V: Population Pharmacokinetics **No. of Hours: 5**

Short Essay **5 Marks**

136. Describe Bayesian theory
137. Explain dosing with feedback.
138. Discuss population pharmacokinetic analysis using NONMEM method.
139. Discuss analysis of population pharmacokinetic data.
140. Discuss about the methods used to obtain the estimates of fixed effects and variability
141. Describe the two-stage approach in population pharmacokinetic analysis
142. Explain non-linear mixed effects modeling approach
143. Give the applications of population pharmacokinetics.
144. Explain the sampling design used in population pharmacokinetic study
145. Describe how population pharmacokinetic data analysis is carried out.
146. Give the reasons for conducting population pharmacokinetic study
147. What are the limitations of population pharmacokinetic approach
148. Explain the difference between traditional pharmacokinetics and population pharmacokinetics.

Short Answers **2 Marks**

149. Define adaptive method in population pharmacokinetics study.
150. Define population pharmacokinetics.
151. Define adaptive method in population pharmacokinetics study.
152. Define population pharmacokinetics.
153. What are the advantages of population pharmacokinetic study over traditional pharmacokinetic study?
154. Define interindividual variation
155. Define within subject variation
156. What is random error?
157. What is residual error?
158. What do you understand by typical value?
159. Define theta, omega, sigma in NONMEM method of analysis
160. List the methods used for the population pharmacokinetic model evaluation
161. What is difference between observed and predicted concentrations?
162. What do you understand by over-estimation?
163. List various softwares used for conducting population pharmacokinetic analysis

164. Give Bayesian equation.
165. What do you understand by Goodness of Fit plot
166. Define FO and FOCE.
167. What do you understand by nested models?
168. What is naïve pool data?
169. Give the advantages of Bayesian method in population pharmacokinetic study
170. What is interoccasion variation?